ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexdomitor 0.1 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
0.1 mg dexmedetomidine hydrochloride equivalent to 0.08 mg dexmedetomidine.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	2.0 mg
Propyl parahydroxybenzoate (E216)	0.2 mg
Sodium chloride	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in dogs and cats.

Deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures.

Premedication in dogs and cats before induction and maintenance of general anaesthesia.

3.3 Contraindications

Do not use in animals with cardiovascular disorders.
Do not use in animals with severe systemic disease or in animals that are moribund.
Do not use in case of known hypersensitivity to the active substance or to any of the excipient(s).

3.4 Special warnings

The administration of dexmedetomidine to puppies younger than 16 weeks and kittens younger than 12 weeks has not been studied.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Treated animals should be kept warm and at a constant temperature, both during the procedure and recovery.

It is recommended that animals are fasted for 12 hours prior to Dexdomitor administration. Water may be given.

After treatment, the animal should not be given water or food before it is able to swallow.

Corneal opacities may occur during sedation. The eyes should be protected by a suitable lubricant.

To be used with precaution in elderly animals.

Nervous, aggressive or excited animals should be given the possibility to calm down before initiation of treatment.

Frequent and regular monitoring of respiratory and cardiac function should be performed. Pulse oximetry may be useful but is not essential for adequate monitoring. Equipment for manual ventilation should be available in case of respiratory depression or apnoea when dexmedetomidine and ketamine are used sequentially to induce anaesthesia in cats. It is also advisable to have oxygen readily available, should hypoxaemia be detected or suspected.

Sick and debilitated dogs and cats should only be premedicated with dexmedetomidine before induction and maintenance of general anaesthesia based on a risk-benefit assessment.

Use of dexmedetomidine as a premedicant in dogs and cats significantly reduces the amount of induction drug required for induction of anaesthesia. Attention should be given during the administration of intravenous induction drugs to effect. Volatile anaesthetic requirements for maintenance anaesthesia are also reduced.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet or the label to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.

Avoid skin, eye or mucosal contact; the use of impermeable gloves is advisable. In case of skin or mucosal contact, wash the exposed skin immediately after exposure with large amounts of water and remove contaminated clothes that are in direct contact with skin. In case of eye contact, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to physicians: Dexdomitor is an α_2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically. The specific α_2-adrenoceptor antagonist, atipamezole, which is approved for use in animals, has been used in humans only experimentally to antagonize dexmedetomidine-induced effects.

People with known hypersensitivity to the active substance or any of the excipients should administer the veterinary medicinal product with caution.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs

Very common (> 1 animal / 10 animals treated):	Bradycardia Cyanotic mucous membranes[2] Pale mucous membranes[2]
Common (1 to 10 animals / 100 animals treated):	Arrhythmia[1]
Rare (1 to 10 animals / 10 000 animals treated):	Pulmonary oedema
Undetermined frequency (cannot be estimated from the available data):	Excitation[1] Heart block[1] High blood pressure[3] Low blood pressure[3] Premature ventricular contractions[1] Supraventricular and nodal arrhythmia[1] Hypersalivation[1] Retching[1] Vomiting[4] Corneal opacity Muscle tremor Sedation prolonged[1] Bradypnoea[1,5] Decreased pulse oxygenation[1] Decreased respiratory rate Irregular breathing[1] Tachypnoea[1,5] Erythema[1] Decreased body temperature Urination[1]

[1]When dexmedetomidine and butorphanol are used concomitantly.

[2]Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation.

[3]Blood pressure will increase initially and then return to normal or below normal.

[4]May occur 5–10 minutes after injection. Some dogs may also vomit at the time of recovery.

[5]When dexmedetomidine is used as a premedicant.

When dexmedetomidine and butorphanol are used concomitantly in dogs, brady- and tachyarrhythmias have been reported. These may include profound sinus bradycardia, 1st and 2nd degree AV block, sinus arrest or pause, as well as atrial, supraventricular and ventricular premature complexes.

When dexmedetomidine is used as a premedicant brady- and tachyarrhythmias have been reported and include profound sinus bradycardia, 1st and 2nd degree AV block and sinus arrest. Supraventricular and ventricular premature complexes, sinus pause and 3rd degree AV block may be observed in rare cases.

Cats

Very common (> 1 animal / 10 animals treated):	Arrhythmia[1] Bradycardia Heart block[2] Vomiting[3] Pale mucous membranes[4] Cyanotic mucous membranes[4]
Common (1 to 10 animals / 100 animals treated):	Supraventricular and nodal arrhythmia[1] Retching[1] Decreased pulse oxygenation[2] Hypothermia[2]
Uncommon (1 to 10 animals / 1 000 animals treated):	Apnoea[2]
Rare (1 to 10 animals / 10 000 animals treated):	Pulmonary oedema
Undetermined frequency (cannot be estimated from the available data):	Extrasystole[2] High blood pressure[5] Low blood pressure[5] Corneal opacity Muscle tremor Bradypnoea[2] Decreased respiratory rate Hypoventilation[2] Irregular breathing[2] Agitation[2]

[1]When dexmedetomidine is used as a premedicant.

[2]When dexmedetomidine and ketamine are used sequentially.

[3]May occur 5–10 minutes after injection. Some cats may also vomit at the time of recovery.

[4]Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation.

[5]Blood pressure will increase initially and then return to normal or below normal.

Intramuscular dosing at 40 micrograms/kg (followed by ketamine or propofol) frequently resulted in sinus bradycardia and sinus arrhythmia, occasionally resulted in 1st degree atrioventricular block, and rarely resulted in supraventricular premature depolarizations, atrial bigeminy, sinus pauses, 2nd degree atrioventricular block, or escape beats/rhythms.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation
The safety of dexmedetomidine has not been established during pregnancy and lactation in the target species. Therefore the use of the product during pregnancy and lactation is not recommended.

Fertility
The safety of dexmedetomidine has not been established in males intended for breeding.

3.8 Interaction with other medicinal products and other forms of interaction

The use of other central nervous system depressants is expected to potentiate the effects of dexmedetomidine and therefore an appropriate dose adjustment should be made. Anticholinergics should be used with caution with dexmedetomidine.

Administration of atipamezole after dexmedetomidine rapidly reverses the effects and thus shortens the recovery period. Within 15 minutes dogs and cats are normally awake and standing.

Cats: After administration of 40 micrograms dexmedetomidine/kg bw intramuscularly concurrently with 5 mg ketamine/kg bw to cats, the maximum concentration of dexmedetomidine increased twofold but there was no effect on T_{max}. The mean half-life of elimination of dexmedetomidine increased to 1.6 h and the total exposure (AUC) increased by 50%.

A dose of 10 mg ketamine/ kg used concurrently with 40 micrograms dexmedetomidine/ kg may cause tachycardia.

For information on adverse reactions, see section 3.6. Adverse events.

For information on target animal safety in cases of overdosing, see section 3.10. Symptoms of overdose.

3.9 Administration routes and dosage

The product is intended for:

- Dogs: intravenous or intramuscular use
- Cats: intramuscular use

The product is not intended for repeat injections.

Dexdomitor, butorphanol and/or ketamine can be mixed in the same syringe as they have been shown to be pharmaceutically compatible.

Dosage: the following doses are recommended:

DOGS:

Dexmedetomidine doses are based on body surface area:

Intravenously: up to 375 micrograms/square metre body surface area
Intramuscularly: up to 500 micrograms/square metre body surface area

When administering in conjunction with butorphanol (0.1 mg/kg) for deep sedation and analgesia, the intramuscular dose of dexmedetomidine is 300 micrograms/square metre body surface area. The premedication dose of dexmedetomidine is 125–375 micrograms/square metre body surface area, administered 20 minutes prior to induction for procedures requiring anaesthesia. The dose should be adjusted to the type of surgery, length of procedure and patient temperament.

Concomitant use of dexmedetomidine and butorphanol produces sedative and analgesic effects beginning no later than 15 minutes after administration. The peak sedative and analgesic effects are reached within 30 minutes after administration. Sedation lasts for at least 120 minutes post administration and analgesia lasts for at least 90 minutes. Spontaneous recovery occurs within 3 hours.

Premedication with dexmedetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. In a clinical study, the requirement for propofol and thiopental was reduced by 30% and 60% respectively. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect. In a clinical study, dexmedetomidine contributed to postoperative analgesia for 0.5–4 hours. However this duration is dependent on a number of variables and further analgesia should be administered in accordance with clinical judgement.

The corresponding doses based on body weight are presented in the following tables. Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

Dog weight	**Dexmedetomidine 125 micrograms/m²**		**Dexmedetomidine 375 micrograms/m²**		**Dexmedetomidine 500 micrograms/m²**	
(kg)	**(mcg/kg)**	**(ml)**	**(mcg/kg)**	**(ml)**	**(mcg/kg)**	**(ml)**
2–3	9.4	0.2	28.1	0.6	40	0.75
3.1–4	8.3	0.25	25	0.85	35	1
4.1–5	7.7	0.35	23	1	30	1.5
5.1–10	6.5	0.5	19.6	1.45	25	2
10.1–13	5.6	0.65	16.8	1.9		
13.1–15	5.2	0.75				
15.1–20	4.9	0.85				

For deep sedation and analgesia with butorphanol

Dog weight	**Dexmedetomidine 300 micrograms/m^2 intramuscularly**	
(kg)	**(mcg/kg)**	**(ml)**
2–3	24	0.6
3.1–4	23	0.8
4.1–5	22.2	1
5.1–10	16.7	1.25
10.1–13	13	1.5
13.1–15	12.5	1.75

For higher weight ranges, use Dexdomitor 0.5 mg/ml and its dosing tables.

CATS:

The dosage for cats is 40 micrograms dexmedetomidine hydrochloride/kg bw equal to a dose volume 0.4 ml Dexdomitor/kg bw when used for non-invasive, mildly to moderately painful procedures requiring restraint, sedation and analgesia.
When dexmedetomidine is used for premedication in cats, the same dose is used. Premedication with dexmedetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. In a clinical study, the requirement for propofol was reduced by 50%. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect.
Anaesthesia can be induced 10 minutes after premedication by intramuscular administration of a target dose of 5 mg ketamine/ kg bw or by intravenous administration of propofol to effect. Dosing for cats is presented in the following table.

Cat weight	**Dexmedetomidine 40 micrograms/kg intramuscularly**	
(kg)	**(mcg/kg)**	**(ml)**
1–2	40	0.5
2.1–3	40	1

For higher weight ranges, use Dexdomitor 0.5 mg/ml and its dosing table.

The expected sedative and analgesic effects are reached within 15 minutes after administration and are maintained up to 60 minutes after administration. Sedation may be reversed with atipamezole. Atipamezole should not be administered prior to 30 minutes following ketamine administration.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Dogs: In cases of overdosage, or if the effects of dexmedetomidine become potentially life-threatening, the appropriate dose of atipamezole is 10 times the initial dose of dexmedetomidine (micrograms/ kg bw or micrograms/ square meter body surface area). The dose volume of atipamezole at the concentration of 5 mg/ml is one fifth (1/5) of the dose volume of Dexdomitor 0.1 mg/ml that was given to the dog, regardless of route of administration of Dexdomitor.

Cats: In cases of overdosage, or if the effects of dexmedetomidine become potentially life-threatening, the appropriate antagonist is atipamezole, administered by intramuscular injection, at the following dose: 5 times the initial dose dexmedetomidine in micrograms/kg bw.
After concurrent exposure to a triple (3X) overdose of dexmedetomidine and 15 mg ketamine/ kg, atipamezole can be administered at the recommended dose level for reversal of effects induced by dexmedetomidine. At high serum concentrations of dexmedetomidine sedation is not increased although the level of analgesia does increase with further dose increases. The dose volume of

atipamezole at the concentration of 5 mg/ml equals one tenth (1/10) the volume of Dexdomitor 0.1 mg/ml that was given to the cat.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05CM18.

4.2 Pharmacodynamics

Dexdomitor contains dexmedetomidine as the active substance, which produces sedation and analgesia in dogs and cats. The duration and depth of the sedation and analgesia are dose-dependent. At maximal effect, the animal is relaxed, recumbent and does not respond to external stimulus.

Dexmedetomidine is a potent and selective α_2-adrenoceptor agonist that inhibits the release of noradrenaline from noradrenergic neurons. Sympathetic neurotransmission is prevented and the level of consciousness decreases. Reduced heart rate and temporary AV-block can be seen after administration of dexmedetomidine. Blood pressure decreases to normal or below normal levels after an initial increase. Respiration rate can occasionally decrease. Dexmedetomidine also induces a number of other α_2-adrenoceptor mediated effects, which include piloerection, depression of motor and secretory functions of the gastrointestinal tract, diuresis and hyperglycaemia.

A slight decrease in temperature may be observed.

4.3 Pharmacokinetics

As a lipophilic compound, dexmedetomidine is well absorbed after intramuscular administration. Dexmedetomidine is also rapidly distributed in the body and penetrates the blood-brain barrier readily. According to studies in rats, the maximum concentration in the central nervous system is several times that of the corresponding concentration in plasma. In the circulation, dexmedetomidine is largely bound to plasma proteins (> 90%).

Dogs: After an intramuscular dose of 50 micrograms/kg a maximum concentration in plasma of about 12 nanograms/ml is reached after 0.6 hours. The bioavailability of dexmedetomidine is 60% and the apparent volume of distribution (Vd) is 0.9 l/kg. The elimination half-life ($t_{1/2}$) is 40–50 minutes.

Major biotransformations in the dog include hydroxylation, glucuronic acid conjugation and N-methylation in the liver. All known metabolites lack pharmacological activity. Metabolites are excreted mainly in the urine and to a lesser extent in the faeces. Dexmedetomidine has a high clearance and its elimination depends on the hepatic blood flow. A prolonged elimination half-life is therefore expected with overdoses or when dexmedetomidine is coadministered with other substances, which affect hepatic circulation.

Cats: The maximum plasma concentration is reached about 0.24 h after intramuscular administration. After a 40 micrograms/kg bw intramuscular dose the C_{max} is 17 nanograms/ml. The apparent volume of distribution (Vd) is 2.2 l/kg and the elimination half-life ($t_{1/2}$) is one hour.

Biotransformations in the cat occur by hydroxylation in the liver. Metabolites are excreted mainly in the urine (51% of the dose), and to a lesser extent in the faeces. As in dogs dexmedetomidine has a high clearance in cats and its elimination depends on the hepatic blood flow. A prolonged elimination half-life is therefore expected with overdoses or when dexmedetomidine is coadministered with other substances, which affect hepatic circulation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.
Dexdomitor is compatible with butorphanol and ketamine in the same syringe at least for two hours.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 3 months at 25 ºC.

5.3 Special precautions for storage

Do not freeze.

5.4 Nature and composition of immediate packaging

Type I glass vial containing 15 ml of solution for injection closed with a bromobutyl rubber stopper and aluminium cap.

Pack sizes:
Cardboard box containing 1 vial
Cardboard box containing 10 vials

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/02/033/003-004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 30/08/2002

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexdomitor 0.5 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
0.5 mg dexmedetomidine hydrochloride equivalent to 0.42 mg dexmedetomidine

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.6 mg
Propyl parahydroxybenzoate (E216)	0.2 mg
Sodium chloride	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in dogs and cats.

Deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures.

Premedication in dogs and cats before induction and maintenance of general anaesthesia.

3.3 Contraindications

Do not use in animals with cardiovascular disorders.
Do not use in animals with severe systemic disease or in animals that are moribund.
Do not use in case of known hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

The administration of dexmedetomidine to puppies younger than 16 weeks and kittens younger than 12 weeks has not been studied.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Treated animals should be kept warm and at a constant temperature, both during the procedure and recovery.

It is recommended that animals are fasted for 12 hours prior to Dexdomitor administration. Water may be given.

After treatment, the animal should not be given water or food before it is able to swallow.

Corneal opacities may occur during sedation. The eyes should be protected by a suitable lubricant.

To be used with precaution in elderly animals.

Nervous, aggressive or excited animals should be given the possibility to calm down before initiation of treatment.

Frequent and regular monitoring of respiratory and cardiac function should be performed. Pulse oximetry may be useful but is not essential for adequate monitoring. Equipment for manual ventilation should be available in case of respiratory depression or apnoea when dexmedetomidine and ketamine are used sequentially to induce anaesthesia in cats. It is also advisable to have oxygen readily available, should hypoxaemia be detected or suspected.

Sick and debilitated dogs and cats should only be premedicated with dexmedetomidine before induction and maintenance of general anaesthesia based on a risk-benefit assessment.

Use of dexmedetomidine as a premedicant in dogs and cats significantly reduces the amount of induction drug required for induction of anaesthesia. Attention should be given during the administration of intravenous induction drugs to effect. Volatile anaesthetic requirements for maintenance anaesthesia are also reduced.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet or the label to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.

Avoid skin, eye or mucosal contact; the use of impermeable gloves is advisable. In case of skin or mucosal contact, wash the exposed skin immediately after exposure with large amounts of water and

remove contaminated clothes that are in direct contact with skin. In case of eye contact, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to physicians: Dexdomitor is an α_2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically. The specific α_2-adrenoceptor antagonist, atipamezole, which is approved for use in animals, has been used in humans only experimentally to antagonize dexmedetomidine-induced effects.

People with known hypersensitivity to the active substance or any of the excipients should administer the veterinary medicinal product with caution.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs

Very common (> 1 animal / 10 animals treated):	Bradycardia Cyanotic mucous membranes[2] Pale mucous membranes[2]
Common (1 to 10 animals / 100 animals treated):	Arrhythmia[1]
Rare (1 to 10 animals / 10 000 animals treated):	Pulmonary oedema
Undetermined frequency (cannot be estimated from the available data):	Excitation[1] Heart block[1] High blood pressure[3] Low blood pressure[3] Premature ventricular contractions[1] Supraventricular and nodal arrhythmia[1] Hypersalivation[1] Retching[1] Vomiting[4] Corneal opacity Muscle tremor Sedation prolonged[1] Bradypnoea[1,5] Decreased pulse oxygenation[1] Decreased respiratory rate

	Irregular breathing[1] Tachypnoea[1,5] Erythema[1] Decreased body temperature Urination[1]

[1]When dexmedetomidine and butorphanol are used concomitantly.

[2]Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation.

[3]Blood pressure will increase initially and then return to normal or below normal.

[4]May occur 5–10 minutes after injection. Some dogs may also vomit at the time of recovery.

[5]When dexmedetomidine is used as a premedicant.

When dexmedetomidine and butorphanol are used concomitantly in dogs, brady- and tachyarrhythmias have been reported. These may include profound sinus bradycardia, 1st and 2nd degree AV block, sinus arrest or pause, as well as atrial, supraventricular and ventricular premature complexes.

When dexmedetomidine is used as a premedicant brady- and tachyarrhythmias have been reported and include profound sinus bradycardia, 1st and 2nd degree AV block and sinus arrest. Supraventricular and ventricular premature complexes, sinus pause and 3rd degree AV block may be observed in rare cases.

Cats

Very common (> 1 animal / 10 animals treated):	Arrhythmia[1] Bradycardia Heart block[2] Vomiting[3] Pale mucous membranes[4] Cyanotic mucous membranes[4]
Common (1 to 10 animals / 100 animals treated):	Supraventricular and nodal arrhythmia[1] Retching[1] Decreased pulse oxygenation[2] Hypothermia[2]
Uncommon (1 to 10 animals / 1 000 animals treated):	Apnoea[2]
Rare (1 to 10 animals / 10 000 animals treated):	Pulmonary oedema

Undetermined frequency (cannot be estimated from the available data):	Extrasystole[2] High blood pressure[5] Low blood pressure[5] Corneal opacity Muscle tremor Bradypnoea[2] Decreased respiratory rate Hypoventilation[2] Irregular breathing[2] Agitation[2]

[1]When dexmedetomidine is used as a premedicant.

[2]When dexmedetomidine and ketamine are used sequentially.

[3]May occur 5–10 minutes after injection. Some cats may also vomit at the time of recovery.

[4]Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation.

[5]Blood pressure will increase initially and then return to normal or below normal.

Intramuscular dosing at 40 micrograms/kg (followed by ketamine or propofol) frequently resulted in sinus bradycardia and sinus arrhythmia, occasionally resulted in 1st degree atrioventricular block, and rarely resulted in supraventricular premature depolarizations, atrial bigeminy, sinus pauses, 2nd degree atrioventricular block, or escape beats/rhythms.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation
The safety of dexmedetomidine has not been established during pregnancy and lactation in the target species. Therefore the use of the product during pregnancy and lactation is not recommended.

Fertility
The safety of dexmedetomidine has not been established in males intended for breeding.

3.8 Interaction with other medicinal products and other forms of interaction

The use of other central nervous system depressants is expected to potentiate the effects of dexmedetomidine and therefore an appropriate dose adjustment should be made. Anticholinergics should be used with caution with dexmedetomidine.

Administration of atipamezole after dexmedetomidine rapidly reverses the effects and thus shortens the recovery period. Within 15 minutes dogs and cats are normally awake and standing.

Cats: After administration of 40 micrograms dexmedetomidine/kg bw intramuscularly concurrently with 5 mg ketamine/kg bw to cats, the maximum concentration of dexmedetomidine increased

twofold but there was no effect on T_{max}. The mean half-life of elimination of dexmedetomidine increased to 1.6 h and the total exposure (AUC) increased by 50%.

A dose of 10 mg ketamine/ kg used concurrently with 40 micrograms dexmedetomidine/ kg may cause tachycardia.

For information on adverse reactions, see section 3.6. Adverse events.

For information on target animal safety in cases of overdosing, see section 3.10. Symptoms of overdose.

3.9 Administration routes and dosage

The product is intended for:

- Dogs: intravenous or intramuscular use
- Cats: intramuscular use

The product is not intended for repeat injections.

Dexdomitor, butorphanol and/or ketamine can be mixed in the same syringe as they have been shown to be pharmaceutically compatible.

Dosage: the following doses are recommended:

DOGS:

Dexmedetomidine doses are based on body surface area:

Intravenously: up to 375 micrograms/square metre body surface area
Intramuscularly: up to 500 micrograms/square metre body surface area

When administering in conjunction with butorphanol (0.1 mg/kg) for deep sedation and analgesia, the intramuscular dose of dexmedetomidine is 300 micrograms/square metre body surface area. The premedication dose of dexmedetomidine is 125–375 micrograms/square metre body surface area, administered 20 minutes prior to induction for procedures requiring anaesthesia. The dose should be adjusted to the type of surgery, length of procedure and patient temperament.

Concomitant use of dexmedetomidine and butorphanol produces sedative and analgesic effects beginning no later than 15 minutes. The peak sedative and analgesic effects are reached within 30 minutes after administration. Sedation lasts for at least 120 minutes post administration and analgesia lasts for at least 90 minutes. Spontaneous recovery occurs within 3 hours.

Premedication with dexmedetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. In a clinical study, the requirement for propofol and thiopental was reduced by 30% and 60% respectively. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect. In a clinical study, dexmedetomidine contributed to postoperative analgesia for 0.5–4 hours. However this duration is dependent on a number of variables and further analgesia should be administered in accordance with clinical judgement.

The corresponding doses based on body weight are presented in the following tables. Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

Dog weight	Dexmedetomidine 125 mcg/m^2		Dexmedetomidine 375 mcg/m^2		Dexmedetomidine 500 mcg/m^2	
(kg)	(mcg/kg)	(ml)	(mcg/kg)	(ml)	(mcg/kg)	(ml)
2–3	9.4	0.04	28.1	0.12	40	0.15
3–4	8.3	0.05	25	0.17	35	0.2
4–5	7.7	0.07	23	0.2	30	0.3
5–10	6.5	0.1	19.6	0.29	25	0.4
10–13	5.6	0.13	16.8	0.38	23	0.5
13–15	5.2	0.15	15.7	0.44	21	0.6
15–20	4.9	0.17	14.6	0.51	20	0.7
20–25	4.5	0.2	13.4	0.6	18	0.8
25–30	4.2	0.23	12.6	0.69	17	0.9
30–33	4	0.25	12	0.75	16	1.0
33–37	3.9	0.27	11.6	0.81	15	1.1
37–45	3.7	0.3	11	0.9	14.5	1.2
45–50	3.5	0.33	10.5	0.99	14	1.3
50–55	3.4	0.35	10.1	1.06	13.5	1.4
55–60	3.3	0.38	9.8	1.13	13	1.5
60–65	3.2	0.4	9.5	1.19	12.8	1.6
65–70	3.1	0.42	9.3	1.26	12.5	1.7
70–80	3	0.45	9	1.35	12.3	1.8
> 80	2.9	0.47	8.7	1.42	12	1.9

For deep sedation and analgesia with butorphanol		
Dog weight	Dexmedetomidine 300 mcg/m^2 intramuscularly	
(kg)	(mcg/kg)	(ml)
2–3	24	0.12
3–4	23	0.16
4–5	22.2	0.2
5–10	16.7	0.25
10–13	13	0.3
13–15	12.5	0.35
15–20	11.4	0.4
20–25	11.1	0.5
25–30	10	0.55
30–33	9.5	0.6
33–37	9.3	0.65
37–45	8.5	0.7
45–50	8.4	0.8
50–55	8.1	0.85
55–60	7.8	0.9
60–65	7.6	0.95
65–70	7.4	1
70–80	7.3	1.1
> 80	7	1.2

CATS:

The dosage for cats is 40 micrograms dexmedetomidine hydrochloride/kg bw equal to a dose volume 0.08 ml Dexdomitor/kg bw when used for non-invasive, mildly to moderately painful procedures requiring restraint, sedation and analgesia.
When dexmedetomidine is used for premedication in cats, the same dose is used. Premedication with dexmedetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. In a clinical study, the requirement for propofol was reduced by 50%. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect.
Anaesthesia can be induced 10 minutes after premedication by intramuscular administration of a target dose of 5 mg ketamine/ kg bw or by intravenous administration of propofol to effect. Dosing for cats is presented in the following table.

Cat weight	**Dexmedetomidine 40 mcg/kg intramuscularly**	
(kg)	**(mcg/kg)**	**(ml)**
1–2	40	0.1
2–3	40	0.2
3–4	40	0.3
4–6	40	0.4
6–7	40	0.5
7–8	40	0.6
8–10	40	0.7

The expected sedative and analgesic effects are reached within 15 minutes after administration and are maintained up to 60 minutes after administration. Sedation may be reversed with atipamezole. Atipamezole should not be administered prior to 30 minutes following ketamine administration.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Dogs: In cases of overdosage, or if the effects of dexmedetomidine become potentially life-threatening, the appropriate dose of atipamezole is 10 times the initial dose of dexmedetomidine (micrograms/ kg bw or micrograms/ square meter body surface area). The dose volume of atipamezole at the concentration of 5 mg/ml equals the dose volume of Dexdomitor that was given to the dog, regardless of route of administration of Dexdomitor.

Cats: In cases of overdosage, or if the effects of dexmedetomidine become potentially life-threatening, the appropriate antagonist is atipamezole, administered by intramuscular injection, at the following dose: 5 times the initial dose dexmedetomidine in micrograms/kg bw.
After concurrent exposure to a triple (3X) overdose of dexmedetomidine and 15 mg ketamine/ kg, atipamezole can be administered at the recommended dose level for reversal of effects induced by dexmedetomidine. At high serum concentrations of dexmedetomidine sedation is not increased although the level of analgesia does increase with further dose increases. The dose volume of atipamezole at the concentration of 5 mg/ml equals one-half the volume of Dexdomitor that was given to the cat.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05CM18.

4.2 Pharmacodynamics

Dexdomitor contains dexmedetomidine as the active substance, which produces sedation and analgesia in dogs and cats. The duration and depth of the sedation and analgesia are dose-dependent. At maximal effect, the animal is relaxed, recumbent and does not respond to external stimulus.

Dexmedetomidine is a potent and selective α_2-adrenoceptor agonist that inhibits the release of noradrenaline from noradrenergic neurons. Sympathetic neurotransmission is prevented and the level of consciousness decreases. Reduced heart rate and temporary AV-block can be seen after administration of dexmedetomidine. Blood pressure decreases to normal or below normal levels after an initial increase. Respiration rate can occasionally decrease. Dexmedetomidine also induces a number of other α_2-adrenoceptor mediated effects, which include piloerection, depression of motor and secretory functions of the gastrointestinal tract, diuresis and hyperglycaemia.

A slight decrease in temperature may be observed.

4.3 Pharmacokinetics

As a lipophilic compound, dexmedetomidine is well absorbed after intramuscular administration. Dexmedetomidine is also rapidly distributed in the body and penetrates the blood-brain barrier readily. According to studies in rats, the maximum concentration in the central nervous system is several times that of the corresponding concentration in plasma. In the circulation, dexmedetomidine is largely bound to plasma proteins (> 90%).

Dogs: After an intramuscular dose of 50 micrograms/kg a maximum concentration in plasma of about 12 ng/ml is reached after 0.6 hours. The bioavailability of dexmedetomidine is 60% and the apparent volume of distribution (Vd) is 0.9 l/kg. The elimination half-life ($t_{1/2}$) is 40–50 minutes.

Major biotransformations in the dog include hydroxylation, glucuronic acid conjugation and N-methylation in the liver. All known metabolites lack pharmacological activity. Metabolites are excreted mainly in the urine and to a lesser extent in the faeces. Dexmedetomidine has a high clearance and its elimination depends on the hepatic blood flow. A prolonged elimination half-life is therefore expected with overdoses or when dexmedetomidine is coadministered with other substances, which affect hepatic circulation.

Cats: The maximum plasma concentration is reached about 0.24 h after intramuscular administration. After a 40 micrograms/kg bw intramuscular dose the Cmax is 17 ng/ml. The apparent volume of distribution (Vd) is 2.2 l/kg and the elimination half-life ($t_{1/2}$) is one hour.

Biotransformations in the cat occur by hydroxylation in the liver. Metabolites are excreted mainly in the urine (51% of the dose), and to a lesser extent in the faeces. As in dogs dexmedetomidine has a high clearance in cats and its elimination depends on the hepatic blood flow. A prolonged elimination half-life is therefore expected with overdoses or when dexmedetomidine is coadministered with other substances, which affect hepatic circulation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.
Dexdomitor is compatible with butorphanol and ketamine in the same syringe at least for two hours.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 3 months at 25 ºC.

5.3 Special precautions for storage

Do not freeze.

5.4 Nature and composition of immediate packaging

Type I glass vial containing 10 ml of solution for injection closed with a bromobutyl rubber stopper and aluminium cap.

Pack sizes:
Cardboard box containing 1 vial
Cardboard box containing 10 vials

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/02/033/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 30/08/2002

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexdomitor 0.1 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
0.1 mg dexmedetomidine hydrochloride equivalent to 0.08 mg dexmedetomidine.

3. PACKAGE SIZE

15 ml
10 x 15 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: intravenous or intramuscular use
Cats: intramuscular use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.
Shelf life after first opening: 3 months at 25 °C.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

14. MARKETING AUTHORISATION NUMBERS

EU/2/02/033/003 (1 vial)
EU/2/02/033/004 (10 vials)

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL (GLASS)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexdomitor

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

dexmedetomidine hydrochloride 0.1 mg/ml

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.
Shelf life after first opening: 3 months at 25 °C.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexdomitor 0.5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
0.5 mg dexmedetomidine hydrochloride equivalent to 0.42 mg dexmedetomidine.

3. PACKAGE SIZE

10 ml
10 x 10 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: intravenous or intramuscular use
Cats: intramuscular use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.
Shelf life after first opening: 3 months at 25 °C.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

14. MARKETING AUTHORISATION NUMBERS

EU/2/02/033/001 (1 vial)
EU/2/02/033/002 (10 vials)

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL (GLASS)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexdomitor

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

dexmedetomidine hydrochloride 0.5 mg/ml

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.
Shelf life after first opening: 3 months at 25 °C.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dexdomitor 0.1 mg/ml solution for injection

2. Composition

Each ml contains:

Active substance:
0.1 mg dexmedetomidine hydrochloride equivalent to 0.08 mg dexmedetomidine.

Excipients:
Methyl parahydroxybenzoate (E 218) 2.0 mg
Propyl parahydroxybenzoate (E 216) 0.2 mg

3. Target Species

Dogs and cats

4. Indications for use

Non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in dogs and cats.
Deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures.
Premedication in dogs and cats before induction and maintenance of general anaesthesia.

5. Contraindications

Do not use in animals with cardiovascular disorders.
Do not use in animals with severe systemic disease or in animals that are moribund.
Do not use in case of known hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
The administration of dexmedetomidine to puppies younger than 16 weeks and kittens younger than 12 weeks has not been studied.

Special precautions for safe use in the target species:
Treated animals should be kept warm and at a constant temperature, both during the procedure and recovery.

Nervous, aggressive or excited animals should be given the possibility to calm down before initiation of treatment.

To be used with precaution in elderly animals.

Corneal opacities may occur during sedation. The eyes should be protected by a suitable lubricant.

Frequent and regular monitoring of respiratory and cardiac function should be performed. Pulse oximetry may be useful but is not essential for adequate monitoring.
Equipment for manual ventilation should be available in case of respiratory depression or apnoea when dexmedetomidine and ketamine are used sequentially to induce anaesthesia in cats. It is also advisable to have oxygen readily available, should hypoxaemia be detected or suspected.

Sick and debilitated dogs and cats should only be premedicated with dexmedetomidine before induction and maintenance of general anaesthesia based on a risk-benefit assessment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.

Avoid skin, eye or mucosal contact; the use of impermeable gloves is advisable. In case of skin or mucosal contact, wash the exposed skin immediately after exposure with large amounts of water and remove contaminated clothes that are in direct contact with skin. In case of eye contact, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to physicians: Dexdomitor is an α_2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically. The specific α_2-adrenoceptor antagonist, atipamezole, which is approved for use in animals, has been used in humans only experimentally to antagonize dexmedetomidine-induced effects.

Persons with known hypersensitivity to the active substance or any of the excipients should administer the product with caution.

Pregnancy and lactation:
The safety of dexmedetomidine has not been established during pregnancy and lactation in the target species. Therefore the use of the product during pregnancy and lactation is not recommended.

Fertility:
The safety of dexmedetomidine has not been established in males intended for breeding.

Interaction with other medicinal products and other forms of interaction:
The use of other central nervous system depressants is expected to potentiate the effects of dexmedetomidine and therefore an appropriate dose adjustment should be made. Use of dexmedetomidine as a premedicant in dogs significantly reduces the amount of induction drug required for induction of anaesthesia. Attention should be given during the administration of intravenous induction drugs to effect. Volatile anaesthetic requirements for maintenance anaesthesia are also reduced.

Anticholinergics should be used with caution with dexmedetomidine.

Cats: After administration of 40 micrograms dexmedetomidine/ kg bw intramuscularly concurrently with 5 mg ketamine /kg bw to cats, the maximum concentration of dexmedetomidine increased

twofold but there was no effect on T_{max}. The mean half-life of elimination of dexmedetomidine increased to 1.6 h and the total exposure (AUC) increased by 50%.

A dose of 10 mg ketamine/kg used concurrently with 40 micrograms dexmedetomidine/ kg may cause tachycardia.

Administration of atipamezole after dexmedetomidine rapidly reverses the effects and thus shortens the recovery period. Within 15 minutes dogs and cats are normally awake and standing

For information on adverse reactions, see section: Adverse events.

Overdose:
In cases of overdosing the following recommendations should be followed:

DOGS: In cases of overdosage, or if the effects of dexmedetomidine become potentially life-threatening, the appropriate dose of atipamezole is 10 times the initial dose of dexmedetomidine (micrograms/ kg bw or micrograms/ square meter body surface area). The dose volume of atipamezole at the concentration of 5 mg/ml is one fifth (1/5) of the dose volume of Dexdomitor 0.1 mg/ml that was given to the dog, regardless of route of administration of Dexdomitor.

CATS: In cases of overdosage, or if the effects of dexmedetomidine become potentially life-threatening, the appropriate antagonist is atipamezole, administered by intramuscular injection, at the following dose: 5 times the initial dose dexmedetomidine in micrograms/kg bw. After concurrent exposure to a triple (3X) overdose of dexmedetomidine and 15 mg ketamine/ kg, atipamezole can be administered at the recommended dose level for reversal of effects induced by dexmedetomidine.
At high serum concentration of dexmedetomidine sedation is not increased although the level of analgesia does increase with further dose increases.
The dose volume of atipamezole at the concentration of 5 mg/ml equals one- tenth (1/10) the volume of Dexdomitor 0.1 mg/ml that was given to the cat.

7. Adverse events

Dogs

Very common (> 1 animal / 10 animals treated):	Bradycardia Cyanotic mucous membranes[2] Pale mucous membranes[2]
Common (1 to 10 animals / 100 animals treated):	Arrhythmia[1]
Rare (1 to 10 animals / 10 000 animals treated):	Pulmonary oedema
Undetermined frequency (cannot be estimated from the available data):	Excitation[1] Heart block[1] High blood pressure[3] Low blood pressure[3] Premature ventricular contractions[1] Supraventricular and nodal arrhythmia[1]

	Hypersalivation[1] Retching[1] Vomiting[4] Corneal opacity Muscle tremor Sedation prolonged[1] Bradypnoea[1,5] Decreased pulse oxygenation[1] Decreased respiratory rate Irregular breathing[1] Tachypnoea[1,5] Erythema[1] Decreased body temperature Urination[1]

[1]When dexmedetomidine and butorphanol are used concomitantly.

[2]Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation.

[3]Blood pressure will increase initially and then return to normal or below normal.

[4]May occur 5–10 minutes after injection. Some dogs may also vomit at the time of recovery.

[5]When dexmedetomidine is used as a premedicant.

When dexmedetomidine and butorphanol are used concomitantly in dogs, brady- and tachyarrhythmias have been reported. These may include profound sinus bradycardia, 1st and 2nd degree AV block, sinus arrest or pause, as well as atrial, supraventricular and ventricular premature complexes.

When dexmedetomidine is used as a premedicant brady- and tachyarrhythmias have been reported and include profound sinus bradycardia, 1st and 2nd degree AV block and sinus arrest. Supraventricular and ventricular premature complexes, sinus pause and 3rd degree AV block may be observed in rare cases.

Cats

Very common (> 1 animal / 10 animals treated):	Arrhythmia[1] Bradycardia Heart block[2] Vomiting[3] Pale mucous membranes[4] Cyanotic mucous membranes[4]
Common (1 to 10 animals / 100 animals treated):	Supraventricular and nodal arrhythmia[1] Retching[1]

	Decreased pulse oxygenation[2] Hypothermia[2]
Uncommon (1 to 10 animals / 1 000 animals treated):	Apnoea[2]
Rare (1 to 10 animals / 10 000 animals treated):	Pulmonary oedema
Undetermined frequency (cannot be estimated from the available data):	Extrasystole[2] High blood pressure[5] Low blood pressure[5] Corneal opacity Muscle tremor Bradypnoea[2] Decreased respiratory rate Hypoventilation[2] Irregular breathing[2] Agitation[2]

[1]When dexmedetomidine is used as a premedicant.

[2]When dexmedetomidine and ketamine are used sequentially.

[3]May occur 5–10 minutes after injection. Some cats may also vomit at the time of recovery.

[4]Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation.

[5]Blood pressure will increase initially and then return to normal or below normal.

Intramuscular dosing at 40 micrograms/kg (followed by ketamine or propofol) frequently resulted in sinus bradycardia and sinus arrhythmia, occasionally resulted in 1st degree atrioventricular block, and rarely resulted in supraventricular premature depolarizations, atrial bigeminy, sinus pauses, 2nd degree atrioventricular block, or escape beats/rhythms.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

The product is intended for:

- Dogs: intravenous or intramuscular use
- Cats: intramuscular use

The product is not intended for repeat injections.

Dexdomitor, butorphanol and/or ketamine can be mixed in the same syringe as they have been shown to be pharmacologically compatible.

The following doses are recommended:

DOGS:

Dexdomitor doses are based on body surface area:

Intravenously: up to 375 micrograms/square metre body surface area
Intramuscularly: up to 500 micrograms/square metre body surface area
When administering in conjunction with butorphanol (0.1 mg/kg) for deep sedation and analgesia, the intramuscular dose of dexmedetomidine is 300 micrograms/square metre body surface area. The premedication dose of dexmedetomidine is 125–375 micrograms/square metre body surface area, administered 20 minutes prior to induction for procedures requiring anaesthesia. The dose should be adjusted to the type of surgery, length of procedure and patient temperament.

Concomitant use of dexmedetomidine and butorphanol produces sedative and analgesic effects beginning no later than 15 minutes after administration. The peak sedative and analgesic effects are reached within 30 minutes after administration. Sedation lasts for at least 120 minutes post administration and analgesia lasts for at least 90 minutes. Spontaneous recovery occurs within 3 hours.

Premedication with dexmedetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. In a clinical study, the requirement for propofol and thiopental was reduced by 30% and 60% respectively. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect. In a clinical study, dexmedetomidine contributed to postoperative analgesia for 0.5–4 hours. However this duration is dependent on a number of variables and further analgesia should be administered in accordance with clinical judgement.

The corresponding doses based on body weight are presented in the following tables. Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

Dog weight	**Dexmedetomidine 125 micrograms/m²**		**Dexmedetomidine 375 micrograms/m²**		**Dexmedetomidine 500 micrograms/m²**	
(kg)	**(mcg/kg)**	**(ml)**	**(mcg/kg)**	**(ml)**	**(mcg/kg)**	**(ml)**
2–3	9.4	0.2	28.1	0.6	40	0.75
3.1–4	8.3	0.25	25	0.85	35	1
4.1–5	7.7	0.35	23	1	30	1.5
5.1–10	6.5	0.5	19.6	1.45	25	2
10.1–13	5.6	0.65	16.8	1.9		
13.1–15	5.2	0.75				
15.1–20	4.9	0.85				

For deep sedation and analgesia with butorphanol		
Dog weight	**Dexmedetomidine 300 micrograms/m² intramuscularly**	
(kg)	**(mcg/kg)**	**(ml)**
2–3	24	0.6

3.1–4	23	0.8
4.1–5	22.2	1
5.1–10	16.7	1.25
10.1–13	13	1.5
13.1–15	12.5	1.75

For higher weight ranges, use Dexdomitor 0.5 mg/ml and its dosing tables.

CATS:

The dosage for cats is 40 micrograms dexmedetomidine hydrochloride/ kg bw equal to a dose volume 0.4 ml Dexdomitor/ kg bw when used for non-invasive, mildly to moderately painful procedures requiring restraint, sedation and analgesia.
When dexmedetomidine is used for premedication in cats, the same dose is used. Premedication with dexmedetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. In a clinical study, the requirement for propofol was reduced by 50%. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect.
Anaesthesia can be induced 10 minutes after premedication by intramuscular administration of a target dose of 5 mg ketamine/kg bw or by intravenous administration of propofol to effect. Dosing for cats is presented in the following table.

Cat weight	**Dexmedetomidine 40 micrograms/kg intramuscularly**	
(kg)	**(mcg/kg)**	**(ml)**
1–2	40	0.5
2.1–3	40	1

For higher weight ranges, use Dexdomitor 0.5 mg/ml and its dosing table.

The expected sedative and analgesic effects are reached within 15 minutes after administration and are maintained up to 60 minutes after administration. Sedation may be reversed with atipamezole. Atipamezole should not be administered prior to 30 minutes following ketamine administration.

9. Advice on correct administration

It is recommended that animals are fasted for 12 hours prior to administration. Water may be given.

After treatment, the animal should not be given water or food before it is able to swallow.

10. Withdrawal periods

Not applicable

11. Special storage precautions

Do not freeze.
Shelf life after first opening the immediate packaging: 3 months at 25 ºC.
Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number: EU/2/02/033/003-004.
Pack sizes: cardboard box with 1 or 10 vials of 15 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing Authorisation Holder
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer responsible for batch release
Orion Corporation
Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

België/Belgique/Belgien
V.M.D. nv
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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dexdomitor 0.5 mg/ml solution for injection

2. Composition

Each ml contains:

Active substance:
0.5 mg dexmedetomidine hydrochloride equivalent to 0.42 mg dexmedetomidine.

Excipients:
Methyl parahydroxybenzoate (E 218) 1.6 mg
Propyl parahydroxybenzoate (E 216) 0.2 mg

3. Target species

Dogs and cats

4. Indications for use

Non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in dogs and cats.
Deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures.
Premedication in dogs and cats before induction and maintenance of general anaesthesia.

5. Contraindications

Do not use in animals with cardiovascular disorders.
Do not use in animals with severe systemic disease or in animals that are moribund.
Do not use in case of known hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
The administration of dexmedetomidine to puppies younger than 16 weeks and kittens younger than 12 weeks has not been studied.

Special precautions for safe use in the target species:
Treated animals should be kept warm and at a constant temperature, both during the procedure and recovery.

Nervous, aggressive or excited animals should be given the possibility to calm down before initiation of treatment.

To be used with precaution in elderly animals.

Corneal opacities may occur during sedation. The eyes should be protected by a suitable lubricant.

Frequent and regular monitoring of respiratory and cardiac function should be performed. Pulse oximetry may be useful but is not essential for adequate monitoring.
Equipment for manual ventilation should be available in case of respiratory depression or apnoea when dexmedetomidine and ketamine are used sequentially to induce anaesthesia in cats. It is also advisable to have oxygen readily available, should hypoxaemia be detected or suspected.

Sick and debilitated dogs and cats should only be premedicated with dexmedetomidine before induction and maintenance of general anaesthesia based on a risk-benefit assessment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.

Avoid skin, eye or mucosal contact; the use of impermeable gloves is advisable. In case of skin or mucosal contact, wash the exposed skin immediately after exposure with large amounts of water and remove contaminated clothes that are in direct contact with skin. In case of eye contact, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to physicians: Dexdomitor is an α_2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically. The specific α_2-adrenoceptor antagonist, atipamezole, which is approved for use in animals, has been used in humans only experimentally to antagonize dexmedetomidine-induced effects.

Persons with known hypersensitivity to the active substance or any of the excipients should administer the product with caution.

Pregnancy and lactation:
The safety of dexmedetomidine has not been established during pregnancy and lactation in the target species. Therefore the use of the product during pregnancy and lactation is not recommended.

Fertility:
The safety of dexmedetomidine has not been established in males intended for breeding.

Interaction with other medicinal products and other forms of interaction:
The use of other central nervous system depressants is expected to potentiate the effects of dexmedetomidine and therefore an appropriate dose adjustment should be made. Use of dexmedetomidine as a premedicant in dogs significantly reduces the amount of induction drug required for induction of anaesthesia. Attention should be given during the administration of intravenous induction drugs to effect. Volatile anaesthetic requirements for maintenance anaesthesia are also reduced.

Anticholinergics should be used with caution with dexmedetomidine.

Cats: After administration of 40 micrograms dexmedetomidine/ kg bw intramuscularly concurrently with 5 mg ketamine /kg bw to cats, the maximum concentration of dexmedetomidine increased

twofold but there was no effect on T_{max}. The mean half-life of elimination of dexmedetomidine increased to 1.6 h and the total exposure (AUC) increased by 50%.

A dose of 10 mg ketamine/kg used concurrently with 40 micrograms dexmedetomidine/ kg may cause tachycardia.

Administration of atipamezole after dexmedetomidine rapidly reverses the effects and thus shortens the recovery period. Within 15 minutes dogs and cats are normally awake and standing.

For information on adverse reactions, see section: Adverse events.

Overdose:
In cases of overdosing the following recommendations should be followed:

DOGS: In cases of overdosage, or if the effects of dexmedetomidine become potentially life-threatening, the appropriate dose of atipamezole is 10 times the initial dose of dexmedetomidine (micrograms/ kg bw or micrograms/ square meter body surface area). The dose volume of atipamezole at the concentration of 5 mg/ml equals the dose volume of Dexdomitor that was given to the dog, regardless of route of administration of Dexdomitor.

CATS: In cases of overdosage, or if the effects of dexmedetomidine become potentially life-threatening, the appropriate antagonist is atipamezole, administered by intramuscular injection, at the following dose: 5 times the initial dose dexmedetomidine in micrograms/kg bw. After concurrent exposure to a triple (3X) overdose of dexmedetomidine and 15 mg ketamine/ kg, atipamezole can be administered at the recommended dose level for reversal of effects induced by dexmedetomidine.
At high serum concentration of dexmedetomidine sedation is not increased although the level of analgesia does increase with further dose increases.
The dose volume of atipamezole at the concentration of 5 mg/ml equals one-half the volume of Dexdomitor that was given to the cat.

7. Adverse events

Dogs

Very common (> 1 animal / 10 animals treated):	Bradycardia Cyanotic mucous membranes[2] Pale mucous membranes[2]
Common (1 to 10 animals / 100 animals treated):	Arrhythmia[1]
Rare (1 to 10 animals / 10 000 animals treated):	Pulmonary oedema
Undetermined frequency (cannot be estimated from the available data):	Excitation[1] Heart block[1] High blood pressure[3] Low blood pressure[3] Premature ventricular contractions[1] Supraventricular and nodal arrhythmia[1]

	Hypersalivation[1] Retching[1] Vomiting[4] Corneal opacity Muscle tremor Sedation prolonged[1] Bradypnoea[1,5] Decreased pulse oxygenation[1] Decreased respiratory rate Irregular breathing[1] Tachypnoea[1,5] Erythema[1] Decreased body temperature Urination[1]

[1]When dexmedetomidine and butorphanol are used concomitantly.

[2]Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation.

[3]Blood pressure will increase initially and then return to normal or below normal.

[4]May occur 5–10 minutes after injection. Some dogs may also vomit at the time of recovery.

[5]When dexmedetomidine is used as a premedicant.

When dexmedetomidine and butorphanol are used concomitantly in dogs, brady- and tachyarrhythmias have been reported. These may include profound sinus bradycardia, 1st and 2nd degree AV block, sinus arrest or pause, as well as atrial, supraventricular and ventricular premature complexes.

When dexmedetomidine is used as a premedicant brady- and tachyarrhythmias have been reported and include profound sinus bradycardia, 1st and 2nd degree AV block and sinus arrest. Supraventricular and ventricular premature complexes, sinus pause and 3rd degree AV block may be observed in rare cases.

Cats

Very common (> 1 animal / 10 animals treated):	Arrhythmia[1] Bradycardia Heart block[2] Vomiting[3] Pale mucous membranes[4] Cyanotic mucous membranes[4]
Common (1 to 10 animals / 100 animals treated):	Supraventricular and nodal arrhythmia[1] Retching[1]

	Decreased pulse oxygenation[2] Hypothermia[2]
Uncommon (1 to 10 animals / 1 000 animals treated):	Apnoea[2]
Rare (1 to 10 animals / 10 000 animals treated):	Pulmonary oedema
Undetermined frequency (cannot be estimated from the available data):	Extrasystole[2] High blood pressure[5] Low blood pressure[5] Corneal opacity Muscle tremor Bradypnoea[2] Decreased respiratory rate Hypoventilation[2] Irregular breathing[2] Agitation[2]

[1]When dexmedetomidine is used as a premedicant.

[2]When dexmedetomidine and ketamine are used sequentially.

[3]May occur 5–10 minutes after injection. Some cats may also vomit at the time of recovery.

[4]Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation.

[5]Blood pressure will increase initially and then return to normal or below normal.

Intramuscular dosing at 40 micrograms/kg (followed by ketamine or propofol) frequently resulted in sinus bradycardia and sinus arrhythmia, occasionally resulted in 1st degree atrioventricular block, and rarely resulted in supraventricular premature depolarizations, atrial bigeminy, sinus pauses, 2nd degree atrioventricular block, or escape beats/rhythms.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

The product is intended for:

- Dogs: intravenous or intramuscular use
- Cats: intramuscular use

The product is not intended for repeat injections.

Dexdomitor, butorphanol and/or ketamine can be mixed in the same syringe as they have been shown to be pharmacologically compatible.
The following doses are recommended:

DOGS:

Dexdomitor doses are based on body surface area:

Intravenously: up to 375 micrograms/square metre body surface area
Intramuscularly: up to 500 micrograms/square metre body surface area

When administering in conjunction with butorphanol (0.1 mg/kg) for deep sedation and analgesia, the intramuscular dose of dexmedetomidine is 300 micrograms/square metre body surface area. The premedication dose of dexmedetomidine is 125–375 micrograms/square metre body surface area, administered 20 minutes prior to induction for procedures requiring anaesthesia. The dose should be adjusted to the type of surgery, length of procedure and patient temperament.

Concomitant use of dexmedetomidine and butorphanol produces sedative and analgesic effects beginning no later than 15 minutes after administration. The peak sedative and analgesic effects are reached within 30 minutes after administration. Sedation lasts for at least 120 minutes post administration and analgesia lasts for at least 90 minutes. Spontaneous recovery occurs within 3 hours.

Premedication with dexmedetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. In a clinical study, the requirement for propofol and thiopental was reduced by 30% and 60% respectively. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect. In a clinical study, dexmedetomidine contributed to postoperative analgesia for 0.5–4 hours. However this duration is dependent on a number of variables and further analgesia should be administered in accordance with clinical judgement.

The corresponding doses based on body weight are presented in the following tables. Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

Dog weight	**Dexmedetomidine 125 mcg/m²**		**Dexmedetomidine 375 mcg/m²**		**Dexmedetomidine 500 mcg/m²**	
(kg)	**(mcg/kg)**	**(ml)**	**(mcg/kg)**	**(ml)**	**(mcg/kg)**	**(ml)**
2–3	9.4	0.04	28.1	0.12	40	0.15
3–4	8.3	0.05	25	0.17	35	0.2
4–5	7.7	0.07	23	0.2	30	0.3
5–10	6.5	0.1	19.6	0.29	25	0.4
10–13	5.6	0.13	16.8	0.38	23	0.5
13–15	5.2	0.15	15.7	0.44	21	0.6
15–20	4.9	0.17	14.6	0.51	20	0.7
20–25	4.5	0.2	13.4	0.6	18	0.8
25–30	4.2	0.23	12.6	0.69	17	0.9
30–33	4	0.25	12	0.75	16	1.0
33–37	3.9	0.27	11.6	0.81	15	1.1
37–45	3.7	0.3	11	0.9	14.5	1.2
45–50	3.5	0.33	10.5	0.99	14	1.3
50–55	3.4	0.35	10.1	1.06	13.5	1.4

55–60	3.3	0.38	9.8	1.13	13	1.5
60–65	3.2	0.4	9.5	1.19	12.8	1.6
65–70	3.1	0.42	9.3	1.26	12.5	1.7
70–80	3	0.45	9	1.35	12.3	1.8
> 80	2.9	0.47	8.7	1.42	12	1.9

For deep sedation and analgesia with butorphanol		
Dog weight	**Dexmedetomidine 300 mcg/m^2 intramuscularly**	
(kg)	**(mcg/kg)**	**(ml)**
2–3	24	0.12
3–4	23	0.16
4–5	22.2	0.2
5–10	16.7	0.25
10–13	13	0.3
13–15	12.5	0.35
15–20	11.4	0.4
20–25	11.1	0.5
25–30	10	0.55
30–33	9.5	0.6
33–37	9.3	0.65
37–45	8.5	0.7
45–50	8.4	0.8
50–55	8.1	0.85
55–60	7.8	0.9
60–65	7.6	0.95
65–70	7.4	1
70–80	7.3	1.1
> 80	7	1.2

CATS:

The dosage for cats is 40 micrograms dexmedetomidine hydrochloride/ kg bw equal to a dose volume 0.08 ml Dexdomitor/ kg bw when used for non-invasive, mildly to moderately painful procedures requiring restraint, sedation and analgesia.
When dexmedetomidine is used for premedication in cats, the same dose is used. Premedication with dexmedetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. In a clinical study, the requirement for propofol was reduced by 50%. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect.
Anaesthesia can be induced 10 minutes after premedication by intramuscular administration of a target dose of 5 mg ketamine/kg bw or by intravenous administration of propofol to effect. Dosing for cats is presented in the following table.

Cat weight	**Dexmedetomidine 40 mcg/kg intramuscularly**	
(kg)	**(mcg/kg)**	**(ml)**
1–2	40	0.1
2–3	40	0.2
3–4	40	0.3

4–6	40	0.4
6–7	40	0.5
7–8	40	0.6
8–10	40	0.7

The expected sedative and analgesic effects are reached within 15 minutes after administration and are maintained up to 60 minutes after administration. Sedation may be reversed with atipamezole. Atipamezole should not be administered prior to 30 minutes following ketamine administration.

9. Advice on correct administration

It is recommended that animals are fasted for 12 hours prior to administration. Water may be given.

After treatment, the animal should not be given water or food before it is able to swallow.

10. Withdrawal periods

Not applicable

11. Special storage precautions

Do not freeze.
Shelf life after first opening the immediate packaging: 3 months at 25 ºC.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number: EU/2/02/033/001-002.
Pack sizes: cardboard box with 1 or 10 vials of 10 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database https://medicines.health.europa.eu/veterinary).

16. Contact details

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Manufacturer responsible for batch release
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Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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