[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fentadon 50 microgram/ml solution for injection/infusion for dogs
SE, DK: Fentadon Vet. 50 microgram/ml solution for injection/infusion for dogs
NO: Fentadon vet 50 microgram/ml solution for injection/infusion for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Fentanyl: 50 microgram
(equivalent to 78.5 microgram of fentanyl citrate)

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	
Hydrochloric acid (for pH adjustment)	
Sodium hydroxide (for pH adjustment)	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For intra-operative analgesia during surgical procedures such as soft tissue and orthopaedic surgery.
For the control of post-operative pain associated with major orthopaedic and soft tissue surgery.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.
Do not use in dogs with cardiac failure, hypotension, hypovolaemia, obstructive airway disease, respiratory depression, hypertension or with a history of epilepsy.
Do not use in animals with severe liver or renal dysfunction.
Refer to sections 3.7 and 3.8.

3.4 Special warnings

The use of this veterinary medicinal product must be preceded by a thorough clinical examination.
Atropine may be used to block the vagal effects.

This veterinary medicinal product should be titrated for the individual animal to an effective dose that provides adequate analgesia and minimises undesirable effects. Animals should be carefully monitored until an effective dose is reached. Due to individual differences in pain sensitivity, the effects of fentanyl may be variable. Older animals may tend to titrate to a lower effective dose than younger animals.
It is important when estimating the required dose for intra-operative analgesia to assess the likely degree of surgical stimulation, the effect of premedication drugs, whether supportive care like endotracheal intubation and ventilatory support may be required, and the duration of the procedure. When estimating the required dose for post-operative analgesia the degree of tissue damage has to be assessed.

3.5 Special precautions for use

Special precautions for safe use in the target species:
If other narcotic or CNS-depressant drugs (e.g. propofol, isoflurane, sevoflurane) are used concurrently with fentanyl the doses of these agents may need to be reduced.
As a class, opioids, including this veterinary medicinal product, may cause hypothermia with duration related to dose, bradypnea, hypotension and bradycardia. Therefore, animals should be continuously monitored for rectal temperature, pulse rate, respiratory rate and heart rhythm during surgical anaesthesia.
In case of renal, cardiac or hepatic dysfunction, hypovolaemia or shock, there may be greater risk associated with the use of the veterinary medicinal product. It is desirable to reduce dosage in case of hypothyroidism and in case of chronic hepatic or renal disease. As with all narcotic analgesics, care should be taken when administering fentanyl to animals with myasthenia gravis.
Facilities for the maintenance of a patent airway, intermittent positive pressure ventilation (IPPV) and oxygen supplementation should be available. When respiratory depression occurs, controlled ventilation should be installed.
As with all potent opioids, profound analgesia is accompanied by respiratory depression, which may persist into or recur in the early post-operative period. The respiratory depressant effects may be more problematic in animals with pre-existing respiratory disease or increased intracranial pressure. The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied. It is imperative to ensure that adequate spontaneous breathing has been established and maintained before discharge from the recovery area whenever large doses of infusions of fentanyl have been administered. The benefit-risk ratio for using the veterinary medicinal product should be made by the attending vet. The pharmacological effects of fentanyl citrate can be reversed by naloxone.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Fentanyl, an opioid, may cause adverse effects after internal exposure, including respiratory depression or apnoea, sedation, hypotension and coma.
The veterinary medicinal product may cause hypersensitivity reactions. Avoid contact with the skin and eyes. Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product. Wash hands after use. Wash any splashes from skin and eyes immediately with large amounts of water. Remove contaminated clothes.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation may occur.
Adverse effects on the foetus cannot be excluded. Pregnant women should avoid handling the veterinary medicinal product. In case of women who are breastfeeding being accidentally exposed, breastfeeding is discouraged for 24 hours, as fentanyl may transfer to breast milk.

To the physician:
Fentanyl is an opioid whose toxicity may cause clinical effects, including respiratory depression or apnoea, sedation, hypotension and coma. When respiratory depression occurs, controlled ventilation should be installed. Administration of the opioid antagonist naloxone to reverse the symptoms is recommended.

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

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Hyperactivity, Irritability, Vocalisation Involuntary defecation, Tongue protrusion, Vomiting Tremor [a], Sedation Urination Increased respiratory rate, Panting Scratching
Common (1 to 10 animals / 100 animals treated):	Respiratory depression [b] Bradycardia [c], Hypotension [d]
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypothermia
Rare (1 to 10 animals / 10,000 animals treated):	Lowered nociceptive thresholds [e]

[a] Tremors of the body.
[b] Can be of long duration and may exhibit a biphasic pattern.
[c] Due to increased cardiac vagal stimulation.
[d] Transient. Following intravenous administration of fentanyl citrate even at doses of 2.5 – 5 µg/kg.
[e] When the effects of the drug dissipate.

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 the veterinary medicinal product has not been established during pregnancy and lactation. The use is not recommended during pregnancy or lactation.
Laboratory studies in rats have not produced any evidence of a teratogenic, foetotoxic or mutagenic effect. Placental transfer of fentanyl occurs. Administration during parturition may cause respiratory depression in the foetus.

3.8 Interaction with other medicinal products and other forms of interaction

Fentanyl is a potent anaesthetic sparing substance. To avoid anaesthetic overdose in dogs treated with the veterinary medicinal product, anaesthetic agents should be administered only until the desired effect is produced.
The veterinary medicinal product should be used with caution in conjunction with morphine or other opioid type analgesics as the effects have not been studied.
The effects of the concomitant use of the veterinary medicinal product and α-adrenergic agonists have not been studied. Therefore, α2-adrenergic agonists should be used with caution in animals dosed with the veterinary medicinal product due to potentially additive or synergistic effects.

3.9 Administration routes and dosage

For intravenous use.
To ensure a correct dosage, body weight should be determined as accurately as possible.
Onset of action is seen within 5 minutes. The duration of the analgesic effect is 20 (lowest recommended dose) to 40 minutes (highest recommended dose).

Fentanyl can be administered according to the following dosage regimen:

Analgesia by Continuous Rate Infusion (CRI)

- 5 - 10 µg/kg (0.1 - 0.2 ml/kg) IV as a bolus, followed by 12 - 24 µg/kg/hr (0.24 - 0.48 ml/kg/hr) IV for intra-operative analgesia as CRI.
- 6 - 10 µg/kg/hr (0.12 - 0.2 ml/kg/hr) IV for subsequent post-operative analgesia as CRI in sedated animals. During post-operative CRI administration of fentanyl, animals should be monitored carefully.

Chemical-physical compatibility has only been demonstrated for dilutions 1:5 with the following solutions for infusion: sodium chloride 0.9%, Ringer's solution and glucose 5%.

The veterinary medicinal product has a narrow margin of safety and it is important to measure the dose accurately to avoid overdosing.

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

A 2 fold overdose as a bolus injection resulted in the effects mentioned in section 3.6. In the event that any of the following observations are made following the application/overdose of the veterinary medicinal product, reversal should be initiated: severe sedation, unconsciousness, seizures, laboured or abdominal breathing or severe hypotension. The specific narcotic antagonist naloxone hydrochloride can be used to counteract respiratory depression. A dose of 0.01 to 0.04 mg/kg is given intravenously and may be repeated at intervals of 2 to 3 minutes if necessary.

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

For administration only by a veterinarian.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN02AB03

4.2 Pharmacodynamics

Fentanyl is a synthetic opioid that is selective for the µ-opioid receptor.
Fentanyl citrate has the ability to produce profound analgesia. It causes only minor heart and circulatory depression.
The principal actions of therapeutic value are analgesia and sedation.
Following intravenous injection fentanyl has a rapid onset of action, although the maximal analgesic and respiratory depressant effects may not occur for several minutes.

4.3 Pharmacokinetics

After intravenous injection the fentanyl plasma concentrations decrease rapidly primarily due to redistribution. In dogs, fentanyl is 60% bound to plasma proteins. Fentanyl has a large volume of

distribution of more than 5 l/kg. The plasma kinetics of fentanyl are independent of the dose in the range of recommended doses.
Fentanyl has a relatively long elimination half-life: 45 minutes to more than 3 hours in dogs. The clearance is high about 40 to 80 ml/min/kg. It is primarily eliminated by metabolism, with hydroxylation and dealkylation being the primary mechanisms, and less than 8% of the total dose is eliminated as unchanged drug. In addition to hepatic metabolism fentanyl may be metabolised in extra hepatic sites and eliminated by extra renal routes.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except the infusion solutions indicated in section 3.9.
The veterinary medicinal product is incompatible with injection fluids containing meloxicam or any other non-aqueous solution.

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: 28 days.
Chemical and physical stability of the dilutions (as indicated in section 3.9) has been demonstrated for 4 hours at 25 °C. From a microbiological point of view the dilutions should be used immediately.

5.3 Special precautions for storage

Do not freeze.

5.4 Nature and composition of immediate packaging

Vials of uncoloured glass type I, filled with 5, 10, 20, 25, 30, 50 or 100 ml.
Teflon-coated chlorobutyl rubber stoppers type I secured with aluminium caps.

Pack sizes:
Cardboard box containing one vial of 5, 10, 20, 25, 30, 50 or 100 ml.
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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:.

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARDBOARD BOX: 5/10/20/25/30/50/100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fentadon 50 microgram/ml solution for injection/infusion

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Fentanyl: 50 microgram (equivalent to 78.5 microgram of fentanyl citrate)

3. PACKAGE SIZE

5/10/20/25/30/50/100 ml

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.
Use by …./…./….

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

[Company logo]

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL LABEL 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fentadon 50 microgram/ml solution for injection/infusion

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Fentanyl: 50 microgram (equivalent to 78.5 microgram of fentanyl citrate)

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Intravenous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.
Use by …./…./….

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

[Company logo]

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL 5/10/20/25/30/50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fentadon

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 microgram fentanyl per ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fentadon 50 microgram/ml solution for injection/infusion for dogs

2. Composition

Each ml contains:

Active substance:
Fentanyl: 50 microgram (equivalent to 78.5 microgram of fentanyl citrate)

Excipients:

Methyl parahydroxybenzoate (E218)	1.6 mg
Propyl parahydroxybenzoate (E216)	0.2 mg

Clear, colourless solution.

3. Target species

Dogs.

4. Indications for use

For intra-operative analgesia during surgical procedures such as soft tissue- and orthopaedic surgery.
For the control of post-operative pain associated with major orthopaedic and soft tissue surgery.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.
Do not use in dogs with cardiac failure, hypotension, hypovolaemia, obstructive airway disease, respiratory depression, hypertension or with a history of epilepsy.
Do not use in animals with severe liver or renal dysfunction.
Refer to “Special warnings” section.

6. Special warnings

Special warnings:
The use of the medicine must be preceded by a thorough clinical examination. Atropine may be used to block the vagal effects.
This veterinary medicinal product should be titrated for the individual animal to an effective dose that provides adequate analgesia and minimises undesirable effects. Animals should be carefully monitored until an effective dose is reached. Due to individual differences in pain sensitivity, the effects of fentanyl may be variable. Older animals may tend to titrate to a lower effective dose than younger animals.

It is important when estimating the required dose for intra-operative analgesia to assess the likely degree of surgical stimulation, the effect of premedication drugs, whether supportive care like endotracheal intubation and ventilatory support may be required, and the duration of the procedure. When estimating the required dose for post-operative analgesia the degree of tissue damage has to be assessed.

Special precautions for safe use in the target species:
If other narcotic or CNS-depressant drugs (e.g. propofol, isoflurane, sevoflurane) are used concurrently with fentanyl the doses of these agents may need to be reduced.
As a class, opioids, including this veterinary medicinal product, may cause hypothermia with duration related to dose, bradypnea, hypotension and bradycardia. Therefore, animals should be continuously monitored for rectal temperature, pulse rate, respiratory rate and heart rhythm during surgical anaesthesia.
In case of renal, cardiac or hepatic dysfunction, hypovolaemia or shock, there may be greater risk associated with the use of the veterinary medicinal product. It is desirable to reduce dosage in case of hypothyroidism and in case of chronic hepatic or renal disease. As with all narcotic analgesics, care should be taken when administering fentanyl to animals with myasthenia gravis.
Facilities for the maintenance of a patent airway, intermittent positive pressure ventilation (IPPV) and oxygen supplementation should be available. When respiratory depression occurs, controlled ventilation should be installed.
As with all potent opioids, profound analgesia is accompanied by respiratory depression, which may persist into or recur in the early post-operative period. The respiratory depressant effects may be more problematic in animals with pre-existing respiratory disease or increased intracranial pressure. The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied. It is imperative to ensure that adequate spontaneous breathing has been established and maintained before discharge from the recovery area whenever large doses of infusions of fentanyl have been administered. The benefit-risk ratio for using the veterinary medicinal product should be made by the attending vet. The pharmacological effects of fentanyl citrate can be reversed by naloxone.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Fentanyl, an opioid, may cause adverse effects after internal exposure, including respiratory depression or apnoea, sedation, hypotension and coma. The veterinary medicinal product may cause hypersensitivity reactions.
Avoid contact with the skin and eyes. Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product. Wash hands after use. Wash any splashes from skin and eyes immediately with large amounts of water. Remove contaminated clothes.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation may occur.
Adverse effects on the foetus cannot be excluded. Pregnant women should avoid handling the veterinary medicinal product. In case of women who are breastfeeding being accidentally exposed, breastfeeding is discouraged for 24 hours, as fentanyl may transfer to breast milk.

To the physician:
Fentanyl is an opioid whose toxicity may cause clinical effects including respiratory depression or apnoea, sedation, hypotension and coma. When respiratory depression occurs controlled ventilation should be installed. Administration of the opioid antagonist naloxone to reverse the symptoms is recommended.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. The use is not recommended during pregnancy or lactation.
Laboratory studies in rats have not produced any evidence of a teratogenic, foetotoxic, or mutagenic effect. Placental transfer of fentanyl occurs. Administration during parturition may cause respiratory depression in the foetus.

Interaction with other medicinal products and other forms of interaction:
Fentanyl is a potent anaesthetic sparing substance. To avoid anaesthetic overdose in dogs treated with the veterinary medicinal product, anaesthetic agents should be administered only until the desired effect is produced.
The veterinary medicinal product should be used with caution in conjunction with morphine or other opioid type analgesics as the effects have not been studied.
The effects of the concomitant use of the veterinary medicinal product and α-adrenergic agonists have not been studied. Therefore, α2-adrenergic agonists should be used with caution in animals dosed with the veterinary medicinal product due to potentially additive or synergistic effects.

Overdose:
A 2 fold overdose as a bolus injection resulted in the effects mentioned in the section 'Adverse reactions'. In the event that any of the following observations are made following the application/overdose of the veterinary medicinal product, reversal should be initiated: severe sedation, unconsciousness, seizures, laboured or abdominal breathing or severe hypotension. The specific narcotic antagonist naloxone hydrochloride can be used to counteract respiratory depression. A dose of 0.01 to 0.04 mg/kg is given intravenously and may be repeated at intervals of 2 to 3 minutes if necessary.

Special restrictions for use and special conditions for use:
For administration only by a veterinarian.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except the infusion solutions indicated in section "Dosage, route and method of administration".
The veterinary medicinal product is incompatible with injection fluids containing meloxicam or any other non-aqueous solution.

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Hyperactivity, Irritability, Vocalisation In voluntary defecation, Tongue protrusion, Vomiting Tremor [a], Sedation Urination Increased respiratory rate, Panting Scratching
Common (1 to 10 animals / 100 animals treated):	Respiratory depression [b] Bradycardia [c], Hypotension [d]
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypothermia
Rare (1 to 10 animals / 10,000 animals treated):	Lowered nociceptive thresholds [e]

[a] Tremors of the body.
[b] Can be of long duration and may exhibit a biphasic pattern.
[c] Due to increased cardiac vagal stimulation.
[d] Transient. Following intravenous administration of fentanyl citrate even at doses of 2.5 – 5 μg/kg.
[e] When the effects of the drug dissipate.

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:

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

For intravenous use.
Onset of action is seen within 5 minutes. The duration of the analgesic effect is 20 (lowest recommended dose) to 40 minutes (highest recommended dose).

Fentanyl can be administered according to the following dosage regimen:

Analgesia by Continuous Rate Infusion (CRI)

- 5 – 10 µg/kg (0.1 -0.2 ml/kg) IV as a bolus followed by 12 – 24 µg/kg/hr (0.24 – 0.48 ml/kg/hr) IV for intra-operative analgesia as CRI.
- 6 – 10 µg/kg/hr (0.12 – 0.2 ml/kg/hr) IV for subsequent post-operative analgesia as CRI in sedated animals. During post-operative CRI administration of fentanyl, animals should be monitored carefully.

Chemical-physical compatibility has only been demonstrated for dilutions 1:5 with the following solutions for infusion: sodium chloride 0.9%, Ringer solution, and glucose 5%.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
This veterinary medicinal product has a narrow margin of safety and it is important to measure the dose accurately to avoid over-dosing.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.
Chemical and physical stability of the dilutions has been demonstrated for 4 hours at 25 °C. From a microbiological point of view the dilutions should be used immediately.

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

Pack sizes:
Cardboard box containing one vial of 5, 10, 20, 25, 30, 50 or 100 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 :

[Company logo]

Manufacturer responsible for batch release:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

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.

17. Other information