LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX WITH 1 VIAL/5 VIALS/6 VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Medeson 1 mg/ml solution for injection for dogs and cats [AT, CY, CZ, DE, EE, EL, ES, HR, IT, LT, LV, PT, RO, SI, SK]
Sedecalm 1 mg/ml solution for injection for dogs and cats [IE, UK]
Medetomidine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Medetomidine hydrochloride 1.0 mg/ml
(equivalent to 0.85 mg of medetomidine)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 vial
5 vials
6 vials

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs: Intramuscular or intravenous use
Cats: Intramuscular, intravenous or subcutaneous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Medetomidine may not provide analgesia throughout the entire sedation period; therefore, the use of additional analgesics should be considered during painful surgical procedures.
α-2 agonists can cause severe adverse reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP: {month/year}
Shelf-life after first opening the container: 28 days
Once broached, use by: …

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.
Keep vial in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.
Esmeralda, 19
E-08950 Eslugues de Llobregat
Barcelona, Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Medeson 1 mg/ml solution for injection for dogs and cats [AT, CY, CZ, DE, EE, EL, ES, HR, IT, LT, LV, PT, RO, SI, SK]
Sedecalm 1 mg/ml solution for injection for dogs and cats [IE, UK]
Medetomidine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Medetomidine hydrochloride 1.0 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Dogs: IM or IV
Cats: IM, IV or SC

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP: {month/year}
Shelf-life after first opening the container: 28 days
Once broached, use by: …

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Medeson 1 mg/ml solution for injection for dogs and cats [AT, CY, CZ, DE, EL, ES, HR, IT, LT, LV, PT, RO, SI, SK]
Medeson, 1 mg/ml solution for injection for dogs and cats [EE]
Sedecalm 1 mg/ml solution for injection for dogs and cats [IE, UK]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda, 19
E-08950 Esplugues de Llobregat (Barcelona) Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Medeson 1 mg/ml solution for injection for dogs and cats [AT, CY, CZ, DE, EL, ES, HR, IT, LT, LV, PT, RO, SI, SK]
Medeson, 1 mg/ml solution for injection for dogs and cats [EE]
Sedecalm 1 mg/ml solution for injection for dogs and cats [IE, UK]
Medetomidine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:
Active substance:
Medetomidine hydrochloride…….1.0 mg
(equivalent to 0.85 mg of medetomidine)

Excipients:
Methyl parahydroxybenzoate (E218)……1.0 mg
Propyl parahydroxybenzoate…….0.2 mg

Clear and colourless solution.

4. INDICATION(S)

Dogs and cats:
- Sedation in order to facilitate the restraint of animals during clinical examinations.
- Premedication prior to general anaesthesia.

5. CONTRAINDICATIONS

Do not use in animals with serious cardiovascular disease, respiratory disease or hepatic or renal disorders.
Do not use in cases of obstructive disorders of the gastrointestinal tract (such as torsion of the stomach, blockage, obstruction of the oesophagus).
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with diabetes mellitus.
Do not use in animals in a state of shock, emaciation or serious debilitation.

Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.
Do not administer concomitantly with sympathomimetics or sulphonamides and trimethoprim.
See section Pregnancy and lactation.

6. ADVERSE REACTIONS

In very rare cases the following adverse reactions may appear:

- Cardiovascular effects such as bradycardia with atrioventricular block (1st and 2nd degree) and occasionally, extrasystoles, vasoconstriction of coronary artery, decreased cardiac output and increase of blood pressure just after the administration of product (followed by a return to the normal value or slightly below).
- Some dogs and most cats will vomit 5 -10 minutes after injection. Cats may also vomit on recovery.
- Pulmonary oedema, respiratory depression and cyanosis, increase of diuresis, hypothermia, sensitivity to loud noises, reversible hyperglycaemia due to a depression of insulin secretion, pain at the injection site and muscle tremors.

In cases of cardiovascular and respiratory depression, assisted ventilation and administration of oxygen may be indicated. Atropine can increase the cardiac rate.

Dogs with a body weight of less than 10 kg may show the undesirable effects mentioned above more often.

Incidents of prolonged sedation and recurrence of sedation after initial recovery have been reported.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs and cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dogs: Intramuscular or intravenous use
For sedation:
The product should be administered at a dose of 10-80 µg of medetomidine hydrochloride per kg of body weight (corresponding to 0.1 – 0.8 ml/ 10 kg body weight).
Maximal effect is obtained within 15-20 minutes. Clinical effect is dose-dependent, lasting 30 to 180 minutes.

For premedication:
The product should be administered at a dose of 10-40 µg medetomidine hydrochloride per kg body weight (corresponding to 0.1-0.4 ml/ 10 kg body weight). The exact dose depends on the combination of drugs used and the dosage(s) of the other drug(s).
The dose should furthermore be adjusted to the type of surgery, length of procedure and patient temperament and weight. Premedication with medetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect. Before using any combinations, product literature for the other products should be observed. See also section Special precautions for use.

Cats: Intramuscular, intravenous or subcutaneous use
For sedation:
The product should be administered at a dose of 50– 150 µg medetomidine hydrochloride per kg body weight (corresponding to 0.05 – 0.15 ml/ kg body weight).

For premedication for anaesthesia:
The product should be administered at a dose of 80 µg medetomidine hydrochloride per kg body weight (corresponding to 0.08 ml/ kg body weight).

Use the table below to determine the correct dosage on the basis of body weight.

	Dogs		**Cats**	
Body weight (kg)	**Sedation (ml)**	**Premedication (ml)**	**Sedation (ml)**	**Premedication (ml)**
1	0.01-0.08	0.01-0.04	0.05-0.15	0.08
2	0.02-0.16	0.02-0.08	0.10-0.30	0.16
3	0.03-0.24	0.03-0.12	0.15-0.45	0.24
4	0.04-0.32	0.04-0.16	0.20-0.60	0.32
5	0.05-0.40	0.05-0.20	0.25-0.75	0.40
6	0.06-0.48	0.06-0.24	0.30-0.90	0.48
7	0.07-0.56	0.07-0.28	0.35-1.05	0.56
8	0.08-0.64	0.08-0.32	0.40-1.20	0.64
9	0.09-0.72	0.09-0.36	0.45-1.35	0.72
10	0.10-0.80	0.10-0.40	0.50-1.50	0.80
12	0.12-0.96	0.12-0.48		
14	0.14-1.12	0.14-0.56		
16	0.16-1.28	0.16-0.64		
18	0.18-1.44	0.18-0.72		
20	0.20-1.60	0.20-0.80		
25	0.25-2.00	0.25-1.00		
30	0.30-2.40	0.30-1.20		
40	0.40-3.20	0.40-1.60		
50	0.50-4.00	0.50-2.00		

The speed of induction is slower when subcutaneous route of administration is used.

9. ADVICE ON CORRECT ADMINISTRATION

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.
The stopper may be safely punctured up to 50 times.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not refrigerate or freeze. Keep vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after "EXP". The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Medetomidine may not provide analgesia throughout the entire sedation period; therefore, the use of additional analgesics should be considered during painful surgical procedures.

Special precautions for use in animals:
A clinical examination should be carried out in all animals before the use of veterinary medicinal products for sedation and/or general anaesthesia.

When the product is used for premedication, the dose of the anaesthetic should be reduced accordingly and titrated to response, due to the considerable variability in requirements between patients. Before using any combinations, the warnings and contraindications in the product literature for the other product(s) should be observed.
Medetomidine can produce respiratory depression; in such cases, manual ventilation and administration of oxygen may be required.

Higher doses of medetomidine should be avoided in large breed dogs. Care should be taken when combining medetomidine with other anaesthetics or sedatives because of its marked anaesthetic sparing effects. Animals should be fasted 12 hours before anaesthesia.

The animal should be placed in a calm and quiet environment to reach a maximum sedative effect. This takes about 10-15 minutes. Do not start any procedure or administer other medicines before maximum sedation is reached.

Treated animals should be kept warm and at a constant temperature, both during the procedure and during recovery. Vomiting and perianesthetic reflux may occasionally lead to regurgitation of gastric contents to the mouth.

Due to decreased tear flow, the eyes should be protected by a suitable lubricant (appropriate ophthalmic ointment or artificial tear solution).

Animals should be allowed to calm down before initiation of treatment.

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

Care should be taken with use of medetomidine in animals with cardiovascular disease, or which are old or in general poor health. Liver and kidney function should be evaluated prior to use.

In order to reduce the recovery time after anaesthesia or sedation, the effect of the product can be reversed by the administration of an alpha-2-antagonist such as atipemazole.

Atipamezole does not reverse the effect of ketamine. As ketamine alone can elicit convulsions in dogs and cramps in cats, alpha-2 antagonists should not be given less than 30-40 min. after the administration of ketamine. It should be considered that bradycardia might persist after reversal.

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

Avoid skin, eye or mucosal contact.

Wash the exposed skin immediately after exposure with large amounts of water.

Remove contaminated clothes that are in direct contact with skin.

In case of accidental contact of the product with eyes, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

Special precautions should be taken in pregnant women handling the product, to avoid self-injection. Uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to physicians:
Medetomidine is an alpha2-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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Therefore, do not use the drug during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
The concomitant administration of other central nervous system depressants should be expected to potentiate the effect of either product and appropriate dose adjustment should be made.
Medetomidine has marked anaesthetic sparing effects.
The dose of compounds such as propofol and volatile anaesthetics should be reduced accordingly.
The effects of medetomidine can be antagonised by the administration of atipamezole.
Bradycardia may be partially prevented by prior administration (at least 5 minutes before) of an anticholinergic agent; however the administration of anticholinergic agents to treat bradycardia either simultaneously with medetomidine, or following sedation with medetomidine, could lead to adverse cardiovascular effects.

Overdose (symptoms, emergency procedures, antidotes)
In cases of overdosage, the principal signs are prolonged anaesthesia or sedation. In some cases, cardiorespiratory effects may occur. The treatment consists of the administration of an alpha-2 antagonist, such as atipamezole, provided that reversal of sedation is not dangerous for the animal (atipamezole does not reverse the effects of ketamine, which used alone can produce convulsions in dogs and cramps in cats). Alpha-2-antagonists should not be given less than 30-40 minutes after the administration of ketamine.
Cardiovascular and/or respiratory impairment should be treated symptomatically providing the

capability of assisted ventilation.
Atipamezole hydrochloride is administered by the intramuscular route at the following dosages: 5 times the initial dose of medetomidine hydrochloride administered to dogs (µg/kg) and 2.5 times for cats. The volume of atipamezole hydrochloride 5 mg/ml is equal to the volume of medetomidine hydrochloride administered in the case of dogs; for cats, the volume of the antagonist should be half that of medetomidine hydrochloride administered.
If it is imperative to reverse bradycardia but to maintain sedation, atropine may be used.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes:
- Carton box with 1 vial of 10 ml
- Carton box with 5 vials of 10 ml
- Carton box with 6 vials of 10 ml

Not all pack sizes may be marketed

For animal treatment only – to be supplied only on veterinary prescription.