1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SEDATOR 1 mg/ml, solution for injection for dogs and cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Medetomidine hydrochloride 1 mg
(equivalent to 0.85 mg medetomidine)

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 mg
Propyl parahydroxybenzoate	0.2 mg
Sodium chloride	
Sodium hydroxide	
Hydrochloric acid	
Water for injections	

Clear and colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Dogs: for restraint, sedation and analgesia associated with clinical examinations and procedures, minor surgery, pre-anaesthesia and as a premedication before thiopentone-halothane general anaesthesia and as a premedicant before general anaesthesia with propofol. In combination with butorphanol for sedation, analgesia and as a premedicant to thiopentone anaesthesia.

Cats: for restraint and sedation. In combination with ketamine for induction of general anaesthesia prior to surgical procedures in the cat. In combination with butorphanol for sedation and analgesia, and combined with both butorphanol and ketamine for general anaesthesia. As a premedication before alphaxalone/alphadolone for general anaesthesia.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use in conjunction with sympathomimetic amines. Care should be taken with the use of medetomidine in animals with cardiovascular disease or in poor general health.
Before using any combinations consult the contraindications and warnings that appear on the other veterinary medicinal products' data sheet.

Medetomidine should not be used with thiopentone or propofol in animals with cardiac or respiratory disease (see also section 3.10).

3.4 Special warnings

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes

MEDETOMIDINE WITH KETAMINE IN CATS
Medetomidine and ketamine are metabolised in the liver and excreted mainly via the kidneys, therefore any pre-existing hepatic or renal pathology must be carefully evaluated before considering this method of anaesthesia. Vomiting prior to onset of anaesthesia occurs in approximately 10% of cases. Laryngeal and pharyngeal reflexes are retained during anaesthesia. The combination is reported to elicit a pain response in some cats when administered intramuscularly. Heart rates will generally fall to approximately 50% of pre-anaesthetic levels and in some cats very slow respiratory rates are observed (4-6 breaths per minute). Where procedures are prolonged, it may be helpful to apply an eye preparation at regular intervals to lubricate the cornea. During and after anaesthesia, treated animals should be kept in a warm and even temperature.
Medetomidine must not be mixed with other ketamine products, with the exception of Vetalar.

MEDETOMIDINE AS A PREMEDICANT BEFORE THIOPENTONE IN DOGS
Anaesthesia being maintained with halothane (with or without nitrous oxide). This regime should not be used in animals with cardiovascular or respiratory disease. Medetomidine and thiopentone are metabolised in the liver and excreted via the kidneys; any pre-existing hepatic or renal pathology must be carefully evaluated before considering this method of anaesthesia.
Medetomidine has marked anaesthetic sparing effects. Therefore, it should be ensured that the dose of thiopentone and halothane is reduced accordingly and is administered with care to minimise the possibility of inadvertent overdosage. Respiratory rates may fall by up to 30% of pre-dose values following administration of medetomidine. Heart rates will fall following the administration of medetomidine and they will not return to presedation levels following induction. Occasionally there will be a transient rise in heart rate associated with induction followed by bradycardia.
During and after anaesthesia, treated animals should be kept in warm and even temperature.

MEDETOMIDINE AS A PREMEDICANT BEFORE PROPOFOL IN DOGS
This regime should not be used in animals with cardiovascular or respiratory disease. Medetomidine and propofol are metabolised in the liver and excreted via the kidneys; any pre-existing hepatic or renal pathology must be carefully evaluated before considering this method of anaesthesia.
Medetomidine has marked anaesthetic sparing effects, therefore it should be ensured that the dose of propofol is reduced accordingly and is administered with care to minimise the possibility of inadvertent overdosage.
Transient apnoea and movement of the forelegs may occur during induction of anaesthesia and in some cases at higher dosages, a decline in arterial oxygen tension may occur. When using this regime dogs should be intubated and oxygen administered during anaesthesia.
During and after anaesthesia, treated animals should be kept in a warm and even temperature.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Care should be taken with the use of medetomidine in animals with cardiovascular disease or in poor general health.
Medetomidine, ketamine and thiopentone are metabolised in the liver and excreted mainly via the kidneys. Pre-existing liver or kidney pathology should be carefully evaluated prior to using these veterinary medicinal products (see also section 3.7 and 3.10).

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

To the user: In case of accidental self-injection or ingestion, 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.
Immediately after exposure, wash the exposed skin with large amounts of fresh water.
In case of accidental eye contact, rinse with large amounts of fresh water. If symptoms occur, seek the advice of a doctor.
If pregnant women handle the veterinary medicinal product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.
To the physician: 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.

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

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bradycardia, Hypertension [a], Hypotension [a] Decreased respiratory rate [b] Hypothermia [c] Vomiting [d] Polyuria [e]

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

[b] In some dogs and cats (see also section 3.10).

[c] Treated animals should be kept in a warm and even temperature during the procedures and for 12 hours after sedation.

[d] Some dogs and most cats vomit 5-10 minutes after injection. Some cats may also vomit on recovery.

[e] May be associated with recovery.

By virtue of this α2-adrenergic activity, medetomidine may also affect cardiac conductivity.

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:
The use of medetomidine in pregnancy has not been monitored in a sufficient number of animals. The use is not recommended during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Medetomidine should not be used in conjunction with sympathomimetic amines. The concomitant use of other central nervous system depressants should be expected to potentiate the effect of either veterinary medicinal product and appropriate dose adjustment should be made.
Medetomidine has marked anaesthetic sparing effects. The dose of compounds such as thiopentone, halothane and propofol should be reduced accordingly.

3.9 Administration routes and dosage

For intramuscular, intravenous and subcutaneous use in dogs, and for intramuscular or subcutaneous use in cats.

Dosage: the following dose ranges are recommended:

Species	Dose	Effect	Volume
Dogs	10 - 30 µg/kg 30 - 80 µg/kg 10 - 20 µg/kg	Slight sedation Moderate to deep sedation and analgesia Pre-anaesthesia	0.1 - 0.3 ml/10 kg 0.3 - 0.8 ml/10 kg 0.1 - 0.2 ml/10 kg
Cats	50 - 100 µg/kg 100 - 150 µg/kg	Moderate sedation Deep sedation	0.25 - 0.5 ml/5 kg 0.50 - 0.75 ml/5 kg

Maximal effect is obtained within 10-15 minutes. The clinically useful effect is dose-dependent, lasting 30-180 minutes, but may be repeated if necessary.
Animals should be fasted for 12 hours prior to anaesthesia.
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

Premedication dosing guide: Medetomidine has marked anaesthetic-sparing effects. It is essential to reduce appropriately the dose of anaesthetic induction and maintenance agents in animals that have been given the veterinary medicinal product.

Dosing guide:

MEDETOMIDINE AS A PREMEDICANT BEFORE THIOPENTONE IN DOGS
Anaesthesia is maintained with halothane, with or without nitrous oxide.
Medetomidine is administered at least 20 minutes before thiopentone (inducing agent) to allow sedation to develop. Guideline doses of thiopentone are as follows:

MEDETOMIDINE		**Thiopentone**
Dose µg/kg	Volume of product in ml/10 kg	Dose of thiopentone in mg/kg
10	0.1	6.9
20	0.2	4.5
40	0.4	2.4

The dose of thiopentone may vary considerably in different animals. The optimum dose of medetomidine is in the range 20-40 µg/kg and is dependent on the temperament of the dog. At higher doses of medetomidine, thiopentone may not be required for intubation.
Thiopentone is administered slowly as a dilute solution, intravenously to effect, over a period of 30-45 seconds. Once jaw relaxation is adequate, tracheal intubation can be undertaken. Onset of unconsciousness may be delayed for up to 1 minute following injection of thiopentone, slow intravenous injection is therefore required as indicated above. After intubation, anaesthesia may be maintained with halothane in oxygen (with or without nitrous oxide) administered to effect. Recovery

from anaesthesia may take from 20 to more than 60 minutes. For recoveries in excess of 1 hour it is advisable to administer atipamezole.

MEDETOMIDINE AS PREMEDICANT BEFORE PROPOFOL IN DOGS

Medetomidine is administered either intravenously at least 10 minutes before intravenous propofol (induction agent) or intramuscularly at least 20 minutes before propofol to allow sedation to develop. Medetomidine may be administered at a dose rate of 10, 20 or 40 micrograms/kg. The following table is a guideline for doses:

MEDETOMIDINE		**Propofol (Induction)**
Dose in µg/kg	Volume of product in ml/10 kg	Dose of propofol in mg/kg
10	0.1	1.5
20	0.2	1.1
40	0.4	1.0

Following premedication with medetomidine, doses of propofol of up to 4 mg/kg administered intravenously have been safely used when a greater depth of anaesthesia is required.

NB. The induction time is increased following premedication, so propofol should be administered by slow intravenous injection and up to 2.5 minutes should be allowed before a further dose is given. Once jaw relaxation is adequate, tracheal intubation can be undertaken. It is advisable to administer oxygen during anaesthesia.

For maintenance of anaesthesia the dose of propofol is markedly reduced by medetomidine premedication. Infusion doses of 0.06 to 0.35 mg/kg/minute will provide stable anaesthesia for dogs sedated with between 40 and 10 µg/kg medetomidine respectively. For intermittent bolus administration, a dose of 1 mg/kg of propofol at intervals of between 4 and 12 minutes will provide stable anaesthesia.

Recovery from anaesthesia may take from 20 to > 60 minutes.

Food should be withheld for 12 hours prior to anaesthesia.

Atipamezole administered in the post-operative phase will hasten the recovery from anaesthesia.

MEDETOMIDINE WITH BUTORPHANOL FOR CANINE SEDATION

Medetomidine and butorphanol can be administered together in the same syringe, by intramuscular or intravenous injection.

Dose rate: Medetomidine 10-25 µg/kg, depending on the degree of sedation required, plus 0.1 mg/kg butorphanol. Allow 20 minutes for sedation to develop before commencing the procedure.

Reversal with an equal volume of Atipamezole to that of the veterinary medicinal product used results in sternal recumbency approximately 5 minutes later and standing approximately a further 2 minutes later.

MEDETOMIDINE WITH BUTORPHANOL FOLLOWED BY THIOPENTONE ANAESTHESIA FOR CANINE SEDATION

Dose rate: Medetomidine 10 µg/kg and butorphanol 0.1 mg/kg

Medetomidine and butorphanol can be administered together in the same syringe, by intramuscular or intravenous injection.

Allow 20 minutes for sedation to develop before administering thiopentone. Atipamezole administered in the post-operative phase will hasten recovery from anaesthesia.

Canine doses (ml) for mild sedation, or premedication prior to thiopentone:

Weight (kg)	**1**	**3**	**5**	**10**	**15**	**20**	**25**	**30**	**35**	**40**
Sedator 1 mg/ml (dose of medetomidine 10 µg/kg)	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40
Butorphanol 10 mg/ml (dose of butorphanol 0.1 mg/kg)	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40

Canine doses (ml) for deep sedation:

Weight (kg)	1	3	5	10	15	20	25	30	35	40
Sedator 1 mg/ml (dose of medetomidine 25 µg/kg)	0.03	0.08	0.13	0.25	0.38	0.50	0.63	0.75	0.88	1.00
Butorphanol 10 mg/ml (dose of butorphanol 0.1 mg/kg)	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40

MEDETOMIDINE WITH BUTORPHANOL FOR FELINE SEDATION

Medetomidine and butorphanol can be administered together in the same syringe, by intramuscular or subcutaneous injection.

Dose rate: Medetomidine 50 µg/kg, depending on the degree of sedation required, plus 0.40 mg/kg butorphanol. Allow 20 minutes for sedation to develop before commencing the procedure.

Local anaesthetic infiltration should be used for wound suturing.

Reversal with half volume of Atipamezole 5 mg/ml to that of the veterinary medicinal product used, results in sternal recumbency approximately 4 minutes later and standing approximately a further 2 minutes later.

Feline doses (ml) for medetomidine/butorphanol sedation:

Weight (kg)	1	1.5	2	2.5	3	3.5	4	4.5	5
Sedator 1 mg/ml (dose of medetomidine 50 µg/kg)	0.05	0.08	0.10	0.13	0.15	0.18	0.20	0.23	0.25
Butorphanol 10 mg/ml (dose of butorphanol 0.4 mg/kg)	0.04	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20

MEDETOMIDINE WITH KETAMINE IN CATS

The agents may be given concomitantly, in the same syringe, by the intramuscular route. To minimise the risk of cross contamination between vials, insert separate needles into each vial for withdrawal. A dose of 80 µg/kg is recommended for medetomidine, with 2.5-7.5 mg/kg ketamine giving onset of anaesthesia in 3-4 minutes and a duration of 30-50 minutes for surgical procedures.

Anaesthesia may be prolonged, if required, with halothane and oxygen, with or without nitrous oxide.

Atropine is not normally necessary when using a medetomidine/ketamine combination. Food should be withheld for 12 hours prior to anaesthesia.

MEDETOMIDINE, BUTORPHANOL AND KETAMINE FOR FELINE ANAESTHESIA

a) Intramuscular

Dosage: Medetomidine 80 µg/kg, butorphanol 0.4 mg/kg and ketamine 5 mg/kg can be given in a single syringe.

Cats become recumbent in 2-3 minutes following injection. Loss of pedal reflex occurs 3 minutes post injection.

Reversal by 200 µg/kg atipamezole results in return of pedal reflex 2 minutes later, sternal recumbency 6 minutes later and standing 31 minutes later.

Feline doses (ml) for intramuscular medetomidine/butorphanol/ketamine anaesthesia:

Weight (kg)	1	1.5	2	2.5	3	3.5	4	4.5	5
Sedator 1 mg/ml (dose of medetomidine 80 µg/kg)	0.08	0.12	0.16	0.20	0.24	0.28	0.32	0.36	0.40
Butorphanol 10 mg/ml (dose of butorphanol 0.4 mg/kg)	0.04	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
Ketamine 100 mg/ml (dose of ketamine 5mg/kg)	0.05	0.075	0.10	0.125	0.15	0.175	0.20	0.225	0.25

b) Intravenous

Dosage: Medetomidine 40 µg/kg, butorphanol 0.1 mg/kg and ketamine from 1.25 to 2.5 mg/kg (depending on depth of anaesthesia required).

Reversal by 100 µg/kg of atipamezole results in return of pedal reflex 4 minutes later, sternal recumbency 7 minutes later and standing 18 minutes later.
Feline doses (ml) for intravenous medetomidine/butorphanol/ketamine anaesthesia:

Weight (kg)	**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**
Sedator 1 mg/ml (dose of medetomidine 40 µg/kg)	0.04	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
Butorphanol 10 mg/ ml (dose of butorphanol 0.1 mg/kg)	0.01	0.02	0.02	0.03	0.03	0.04	0.04	0.05	0.05
EITHER Ketamine 100 mg/ml (dose of ketamine 1.25 mg/kg)	0.01	0.02	0.03	0.03	0.04	0.04	0.05	0.06	0.06
OR Ketamine 100 mg/ml (dose of ketamine 2.5 mg/kg)	0.03	0.04	0.05	0.06	0.08	0.09	0.10	0.11	0.13

Approximate time scales in intravenous medetomidine/butorphanol/ketamine anaesthesia:

Ketamine dose	Time to recumbency	Time to loss of pedal reflex	Time to return of pedal reflex	Time to sternal recumbency	Time to standing
1.25 mg/kg	32 secs	62 secs	26 mins	54 mins	74 mins
2.5 mg/kg	22 secs	39 secs	28 mins	62 mins	83 mins

MEDETOMIDINE FOLLOWED BY ALPHAXALONE/ALPHADOLONE FOR GENERAL ANAESTHESIA
Dosage: Administer medetomidine 80 µg/kg by intramuscular or subcutaneous injection. 15-60 minutes later administer 2.5-5.0 mg/kg alphaxalone/alphadolone intravenously. Anaesthesia may be maintained by further intravenous injections of alphaxalone/alphadolone, or by administration of halothane in oxygen.
Feline doses (ml) for medetomidine/alphaxalone/alphadolone anaesthesia:

Weight (kg)		**1**	**1.5**	**2**	**2.5**	**3**	**3.5**	**4**	**4.5**	**5**
Sedator 1 mg/ml (medetomidine)	80 µg/kg	0.08	0.12	0.16	0.20	0.24	0.28	0.32	0.36	0.40
Alphaxalone 9 mg/ml /Alphadolone 3 mg/ml	minimum dose = 2.5 mg/kg	0.21	0.31	0.42	0.52	0.63	0.73	0.83	0.94	1.04
Alphaxalone 9 mg/ml /Alphadolone 3 mg/ml	maximum dose = 5 mg/kg	0.42	0.63	0.83	1.04	1.25	1.46	1.67	1.88	2.08

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

In cases of overdosage, or if the effects of medetomidine become life-threatening, the appropriate dose of atipamezole is recommended provided that reversal of sedation and analgesia is not dangerous to the patient. For example, atipamezole does not reverse the effects of ketamine. If it is imperative to reverse bradycardia but to maintain sedation, atropine may be used.

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

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05CM91

4.2 Pharmacodynamics

Medetomidine is a potent and highly selective α2-adrenoreceptor agonist with both central and peripheral activity, and acting both presynaptically and postsynaptically. Its primary effects are sedative and analgesic resulting from its central depressant activity.
It has no local anaesthetic properties. Like other compounds of its class there are secondary effects, including bradycardia. Blood pressure is increased but then returns to normal or just below. Body temperature is decreased in a dose dependent manner and intestinal motility is also reduced.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Medetomidine must not be mixed with other veterinary medicinal products with the exception of Vetalar and Torbugesic injection.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton.
This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

Clear colourless, sterile aqueous solution are presented in a Type I clear glass vials of 5, 10 and 20 ml capacity, each packed in a cardboard box. Vials are fitted with a teflon coated halogenated rubber stopper and sealed with an aluminium cap.
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

Eurovet Animal Health B.V

7. MARKETING AUTHORISATION NUMBER(S)

VPA10989/057/001

8. DATE OF FIRST AUTHORISATION

26/09/2008

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

30/09/2024

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).