SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dorbene vet 1 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Medetomidine hydrochloride 1.0 mg

(equivalent to 0.85 mg medetomidine)

Excipient:

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)	1.0 mg
Propyl parahydroxybenzoate	0.2 mg
Sodium chloride	
Hydrochloric acid (for pH-adjustment)	
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

In dogs and cats:
Sedation to facilitate handling. Premedication prior to general anaesthesia.
In cats:
In combination with ketamine for general anaesthesia for minor surgical procedures of short duration.

3.3 Contraindications

Do not use in animals with:
- Severe cardiovascular disease or respiratory diseases or impaired liver or kidney function.
- Mechanical disturbances of the gastro-intestinal tract (torsio ventriculi, incarcerations,
  oesophageal obstructions).
- Diabetes mellitus.
- State of shock, emaciation or serious debilitation.

Do not use concomitantly with sympathomimetic amines.
Do not use in cases of hypersensitivity to the active substance or to any other excipients.
Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.
See also section 3.7

3.4 Special warnings

Medetomidine may not provide analgesia throughout the entire period of sedation, therefore consideration should be given to providing additional analgesia for painful procedures.

3.5 Special precautions for use

Special precautions for safe use in the target species:

A clinical examination should be carried out in all animals before the use of veterinary medicinal products for sedation and/or general anaesthesia. Higher doses of medetomidine should be avoided in large breed dogs. Care should be taken when combining medetomidine with other anaesthetics or sedatives (e.g. ketamine, thiopental, propofol, halothane), because of its marked anaesthetic sparing effects. The dose of the anaesthetic should be reduced accordingly and titrated to response due to considerable variability in requirements between patients. Before using any combinations, the warnings and contra-indications in the product literature for the other products should be observed.
Animals should be fasted 12 hours before anaesthesia.
The animal should be placed in a calm and quiet surrounding to let the sedation gain its maximum effect.
This takes about 10 – 15 minutes. One should not start any procedure or give other medicines before maximum sedation is reached.
Treated animals should be kept warm and at a constant temperature, both during the procedure and recovery. The eyes should be protected by a suitable lubricant.
Nervous, aggressive or excited 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 elderly or in general poor health. Liver and kidney function should be evaluated prior to use.

Medetomidine may cause respiratory depression and under these circumstances, manual ventilation and oxygen may be administered.
To reduce the recovery time following anaesthesia or sedation the effect of the veterinary medicinal product can be reversed by administration of an alpha-2 antagonist e.g. atipamezole or yohimbine. As ketamine alone can elicit cramps, alpha-2 antagonists should be administered not before 30-40 min. after ketamine. For dosage directions, see section 3.9.

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 label to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.
Care should be taken to avoid accidental self-injection, as well as contact with the skin, eyes and mouth.
Wash the exposed skin immediately after exposure with large amounts of water.
Remove contaminated clothes that are in direct contact with skin.
In the case of accidental contact of the product with eyes, 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.
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 :

Common (1 to 10 animals / 100 animals treated):	Bradycardia, Heart block 1st degree, Heart block 2nd degree, Extrasystole, Vasoconstriction of coronary artery, Cardiac depression[1], High blood pressure[2] Bradypnoea
Uncommon (1 to 10 animals / 1,000 animals treated):	Emesis[3] Increased sensitivity to sound, Muscle tremor Increased urine volume[4] Hypothermia, Cyanosis Respiratory depression Injection site pain
Rare (1 to 10 animals / 10,000 animals treated):	Pulmonary oedema
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hyperglycaemia[5]

[1] Decreased cardiac output. In circulatory and respiratory depression manual ventilation and an oxygen supplement may be indicated. Atropine may increase the cardiac rate.

[2] Blood pressure will increase initially after administration and then return to normal, or slightly below normal.

[3] Particularly in cats. This occurs within a few minutes of administration. Cats may also vomit on recovery.

[4] Due to increased diuresis

[5] Reversible. In individual cases, due to depression of insulin secretion.

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

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

The safety of this veterinary medicinal product has not been established during pregnancy and lactation. Therefore it should not be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

The concomitant use of other CNS depressants should be expected to potentiate the effect of either active substance. Appropriate dose adjustments should be made.
Medetomidine has marked anaesthetic sparing effects. See also section 43.5.
The effects of medetomidine may be antagonized by administration of atipamezole or yohimbine. See also section 3.10.
Do not use concomitantly with sympatomimetic amines or sulfamides + trimethoprim.

3.9 Administration routes and dosage

Dogs: Intramuscular or intravenous use.
Cats: Intramuscular and subcutaneous use.

Dogs:
For sedation the veterinary medicinal product should be administered at the rate of 750 µg medetomidine hydrochloride i.v. or 1000 µg medetomidine hydrochloride i.m. per square meter of body surface, corresponding to dose of 20-80 µg medetomidine hydrochloride per kg body weight.
Use the table below to determine the correct dosage on the basis of body weight:
Maximal effect is obtained within 15-20 minutes. Clinical effect is dose-dependent, lasting from 30 – 180 minutes.

Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

The veterinary medicinal product dosages for sedation in ml and corresponding amount of medetomidine hydrochloride in µg /kg bw. For pre-medication use 50% of the dose indicated in the table:

body weight (kg)	intravenous injection (ml)	corresponding to (µg/kg bw)	Intramuscular injection (ml)	corresponding to (µg/kg bw)
1	0.08	80.0	0.10	100.0
2	0.12	60.0	0.16	80.0
3	0.16	53.3	0.21	70.0
4	0.19	47.5	0.25	62.5

5	0.22	44.0	0.30	60.0
6	0.25	41.7	0.33	55.0
7	0.28	40.0	0.37	52.9
8	0.30	37.5	0.40	50.0
9	0.33	36.7	0.44	48.9
10	0.35	35.0	0.47	47.0
12	0.40	33.3	0.53	44.2
14	0.44	31.4	0.59	42.1
16	0.48	30.0	0.64	40.0
18	0.52	28.9	0.69	38.3
20	0.56	28.0	0.74	37.0
25	0.65	26.0	0.86	34.4
30	0.73	24.3	0.98	32.7
35	0.81	23.1	1.08	30.9
40	0.89	22.2	1.18	29.5
50	1.03	20.6	1.37	27.4
60	1.16	19.3	1.55	25.8
70	1.29	18.4	1.72	24.6
80	1.41	17.6	1.88	23.5
90	1.52	16.9	2.03	22.6
100	1.63	16.3	2,18	21.8

For premedication the veterinary medicinal product should be administered at a dosage of 10-40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1-0.4 ml Dorbene vet 1 mg/ml per 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 3.5.

Cats:
For moderate-deep sedation and restraint of cats the veterinary medicinal product should be administered at a dosage of 50 – 150 µg medetomidine hydrochloride /kg bw (corresp. to 0.05 – 0.15 ml veterinary medicinal product / kg bw). The speed of induction is slower when subcutaneous route of administration is used.

For anaesthesia the veterinary medicinal product should be administered at a dosage of 80 µg medetomidine hydrochloride / kg bw (corresp. to 0.08 ml veterinary medicinal product / kg bw) and 2.5 to 7.5 mg ketamine / kg bw. Using this dosage anaesthesia occurs within 3 – 4 minutes and is apparent for 20 – 50 minutes. For longer lasting procedures administration has to be repeated by using ½ of the initial dose (i.e. 40 µg medetomidine hydrochloride (corresp. to 0.04 ml veterinary medicinal product / kg bw) and 2.5 - 3.75 mg ketamine / kg bw) or 3.0 mg ketamine / kg bw alone. Alternatively, for longer lasting procedures anaesthesia may be extended by use of the inhalation agents isoflurane or halothane, with oxygen or oxygen/nitrous oxide. See section 3.5

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

Overdose will cause delayed recovery after sedation or anaesthesia. In some cases circulatory or respiratory depression may also occur. For treatment of these cardio-respiratory effects of an overdose it is recommended to administer an alpha-2 antagonist e.g. atipamezole or yohimbine, provided that reversal of sedation is not dangerous to the patient (atipamezole does not reverse the effects of ketamine which may cause seizures in dogs and elicit cramps in cats when used alone). Alpha-2 antagonists should be administered not before 30-40 min. after ketamine. In dogs, the dose of atipamezole is 5 times that for medetomidine. For example, if 1ml veterinary medicinal product (1mg medetomidine) has been administered, a dose of 5 mg atipamezole is required. In cats, the dose of atipamezole is 2.5 times that for medetomidine. For example, if 1 ml veterinary medicinal product (1 mg medetomidine) has been administered, a dose of 2.5 mg atipamezole is required.
If it is imperative to reverse bradycardia but maintain sedation, atropine may be used.

In cases of delayed recovery, care should be taken to ensure that the animal remains quiet and warm.
Depending on the situation, the animal may also be ventilated with oxygen and receive intravenous fluids to prevent hypovolaemia. The maintenance of body temperature during sedation and recovery is especially important; in cases of hypothermia, increasing the body to temperature to the normal level for the particular species will hasten recovery.

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

<To be completed in accordance to national requirements>

3.12 Withdrawal periods

Not applicable

4. PHARMACOLOGICALINFORMATION

4.1 ATCvet code:QN05CM91

4.2 Pharmacodynamics

The active ingredient of the veterinary medicinal product is medetomidine (R,S)-4-[1-(2,3-dimethylphenyl)-ethyl)]-imidazole-hydrochloride (INN: Medetomidine), a sedative compound with analgesic and myorelaxing properties. Medetomidine is a selective, specific and highly efficacious alpha-2-receptor agonist. The activation of alpha-2 receptors leads to a decrease in release and turnover of norepinephrine in the central nervous system, leading to sedation, analgesia and bradycardia. In the periphery medetomidine causes vasoconstriction via stimulation of postsynaptic alpha-2 adrenoceptors, leading to a transient arterial hypertension. Within 1 – 2 hours arterial blood pressure falls back to normotension or slight hypotension. The respiratory rate may be transiently decreased. Depth and duration of sedation and analgesia are dose related. Profound sedation and recumbency, with reduced sensitivity to environmental stimuli (sounds, etc.), are seen with medetomidine. Medetomidine acts synergistically with ketamine and opiates, such as fentanyl, leading to better anaesthesia. The amount of volatile anaesthetics, such as halothane, will be reduced by medetomidine. Beside its sedative, analgesic and myo-relaxing properties, medetomidine also exerts hypothermic and mydriatic effects, inhibits salivation and decreases intestinal motility.

4.3 Pharmacokinetics

After intramuscular administration medetomidine is rapidly and nearly completely absorbed from the injection site and pharmacokinetics is very similar to intravenous administration. Maximal plasma concentrations are reached within 15 and 20 minutes. Plasma half-life is considered to be 1.2 hours in the dog and 1.5 hours in the cat. Medetomidine is mainly oxidised in the liver, a smaller amount undergoes methylation in the kidneys. Metabolites will be excreted mainly via urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

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 in order to protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box with one colourless type II glass vial of 10 ml with a teflon-coated type I chlorobutyl stopper and an aluminium cap.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Laboratorios SYVA S.A.

7. MARKETING AUTHORISATION NUMBER

Vm 31592/4000

8. DATE OF FIRST AUTHORISATION

6 December 2007

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

July 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 03 November 2025