

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormilan 1 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Medetomidine hydrochloride1.0 mg
(equivalent to medetomidine0.85 mg)

3. PACKAGE SIZE

10 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

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

7. WITHDRAWAL PERIOD

Not applicable.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days
Once broached, use by

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
Protect from light.
Protect from frost.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Alpha-2-agonists can cause serious adverse reactions. 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

VETPHARMA ANIMAL HEALTH, S.L.

14. MARKETING AUTHORISATION NUMBER

Vm 32509/4001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS
VIAL OF 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormilan

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains :

Medetomidine hydrochloride1.0 mg
(equivalent to medetomidine0.85 mg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dormilan 1 mg/ml solution for injection for dogs and cats

2. Composition

Each ml contains:

Active substance:

Medetomidine hydrochloride1.0 mg
(equivalent to medetomidine0.85 mg)

Excipients:

Methyl parahydroxybenzoate (E218)1.0 mg
Propyl parahydroxybenzoate0.2 mg

Clear and colourless solution and practically free from particles.

3. Target species

Dogs and cats.

4. Indications for use

In 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 case of mechanical disorders of gastrointestinal tract (torsion of the stomach, imprisonment, obstruction of the oesophagus).

Do not administer in conjunction with sympathomimetic amines.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients..

Do not use in animals with diabetes mellitus.

Do not use in animals with state of shock, emaciation or serious debilitation.

Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.

6. Special warnings

Special precautions for safe use in the target species:

It is possible that medetomidine does not provide analgesia throughout the entire sedation period. The use of additional analgesics should be considered during painful surgical procedures.

During its use in premedication, the dosage of anaesthetic will be reduced in proportion and established according to the reaction of the animal, depending on the variability of response between animals. Special warnings and contraindications included in the literature of the other products should be respected before carrying out any association.

Medetomidine can produce respiratory depression; in such case, manual ventilation and administration of oxygen may be conducted.

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 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 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 given the possibility 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.

In order to reduce the recovery time after anaesthesia or sedation, the effect of medetomidine 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 cramps, alpha-2 antagonists should not be given less than 30-40 min. after the administration of ketamine.

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

In the 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.

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.

Advice to doctors:

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 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 effects of medetomidine can be antagonised by the administration of atipamezole.

Do not administer concomitantly with sympathomimetics or sulfamides and trimethoprim.

Overdose:

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, 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.

Atipamezole hydrochloride is administered by intramuscular route at the following dosage: 5 times the initial dose of medetomidine hydrochloride administered to dogs ($\mu\text{g}/\text{kg}$) and 2.5 times for cats. The volume of atipamezole hydrochloride 5 mg/ml is equal to volume of drug administered to dogs; for cats half of this volume should be used.

If it is imperative to reverse bradycardia but to maintain sedation, atropine may be used.

Major incompatibilities:

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

7. Adverse events

Cats and dogs:

Very rare (< 1 animal / 10 000 animals treated, including isolated reports): Bradycardia, Hypotension, , cardiac depression ¹ , Emesis ² , Increased sensitivity to sound, Hypothermia, Cyanosis, Muscle tremors, Respiratory depression ¹ , Pulmonary oedema
Undetermined frequency (cannot be estimated from the available data): Extrasystole, Heart block 1 st degree, Heart block 2 nd degree, Coronary artery disorder (vasoconstriction), Cardiac disorder (decreased cardiac output), High blood pressure ³ , Increased urine volume (increased diuresis), Injection site pain, Hyperglycaemia ⁴ (reversible)

¹ Assisted ventilation and administration of oxygen may be indicated. Atropine can increase the cardiac rate.

² 5-10 minutes after injection. Cats may also vomit on recovery.

³ Occurs just after the administration of the product and then returns to the normal value or slightly below

⁴ Due to a depression of insulin secretion.

Dogs weighing less than 10 kg can present frequently with the above-mentioned adverse reactions.

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Dogs: intramuscular or intravenous use

For sedation:

For sedation the product should be administered at the rate of 15-80 µg of medetomidine hydrochloride per kg of body weight I.V., or 20-100 µg of medetomidine hydrochloride per kg of body weight I.M.

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 30 to 180 minutes.

The veterinary medicinal product dosages in ml and corresponding amount of medetomidine hydrochloride in µg /kg bw:

body weight [kg]	i.v.- Injection [ml]	corresp. to [µg/kg bw]	i.m.- Injection [ml]	corresp. 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:

10-40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1-0.4 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.

Cats: intramuscular injection, intravenous injection and subcutaneous use

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

9. Advice on correct administration

None.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not refrigerate or freeze.
Protect from light.
Protect from frost.

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

12. Special precautions for the disposal

Medicines should not be disposed of via wastewater.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 32509/4001
Pack sizes:
Box containing 1 x 10 ml vial

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L.
Gran Via Carles III, 98, 7a
08028 Barcelona
Spain

Manufacturer responsible for batch release:
INDUSTRIAL VETERINARIA, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat
Spain

Local representative and contact details to report suspected adverse reactions:
LINTBELLS LIMITED
West Barn, Fairclough Hall Farm, Halls Green, Weston Hitchin
Hertfordshire SG4 7DP

17. Other information

POM-V

Gavin Hall

Approved 16 February 2026