

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dormilan 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 medetomidine.....)	0.85 mg)

#### **Excipients:**

<b>Qualitative composition of excipients and other constituents</b>	<b>Quantitative composition if that information is essential for proper administration of the veterinary medicinal product</b>
Methyl parahydroxybenzoate (E218)	1.0 mg
Propyl parahydroxybenzoate (E216)	0.2 mg
Sodium chloride	
Water for injections	

Solution for injection.

Clear and colourless solution and practically free from particles.

### **3. CLINICAL INFORMATION**

#### **3.1. Target species**

Dogs and cats.

#### **3.2. Indications for use for each target species**

In dogs and cats:

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

#### **3.3. 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.

See Section 3.7.

### **3.4. Special warnings**

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.

### **3.5. Special precautions for use**

Special precautions for safe use in the target species:

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 case of accidental oral intake or self-injection, 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.

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.

### 3.6. Adverse events

Cats and dogs:

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

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

<sup>2</sup> 5-10 minutes after injection. Cats may also vomit on recovery.

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

<sup>4</sup> Due to a depression of insulin secretion.

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

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 package leaflet for respective contact details.

### 3.7. Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

Do not use the drug during pregnancy and lactation.

### 3.8. 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 (see section 4.5 of the SPC).

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

Do not administer concomitantly with sympathomimetics or sulfamides and trimethoprim.

### **3.9. Administration routes and dosage**

#### ***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. See also section 4.5.

**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.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and 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, 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 (µg/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.

### **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: QN05CM91**

### **4.2. Pharmacodynamics**

Medetomidine is a sedative component which presents analgesic and myorelaxant properties. It is a selective agonist, specific and particularly effective for alpha-2-adrenergic receptors. The activation of these receptors induces a decrease in the release and turnover of noradrenalin in central nervous system which is declared by means of sedation, analgesia and bradycardia. At peripheral level, medetomidine causes vasoconstriction by stimulation of post-synaptic alpha-2-adrenergic receptors, which produce a transitory hypertension. Blood pressure returns to normal levels,

even to a moderate hypotension within 1 to 2 hours. Respiratory rate can be reduced temporarily.

The time and depth of sedation and analgesia are dose dependent. When the effect is maximum, the animal is relaxed and does not respond to external stimulation. Medetomidine acts in a synergic manner with ketamine or opiates, such as fentanyl, resulting in a better anaesthesia. The necessary amount of volatile anaesthetics (e.g. halothane) is reduced by medetomidine. In addition to its sedative, analgesia and myorelaxant properties, medetomidine also exerts hypothermic and mydriatic effects, inhibits the salivation and decreases intestinal motility.

#### **4.3. Pharmacokinetics**

After intramuscular injection, medetomidine is rapidly and almost completely absorbed in the site of injection and pharmacokinetics is very similar to that observed after intravenous injection. Maximum plasma concentrations are reached within 15 to 20 minutes. Estimated plasma half-life is 1.2 hours for dogs and 1.5 hours for cats. Medetomidine is mainly oxidised in the liver, while a small amount is methylated in the kidney. Metabolites are primarily excreted in 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: 3 years.  
Shelf-life after first opening the immediate packaging: 28 days

#### **5.3. Special precautions for storage**

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

#### **5.4. Nature and composition of immediate packaging**

Type I clear glass vials of 10 ml capacity. Vials are fitted with a bromobutyl stopper and sealed with an aluminium cap. Vials are packed in a cardboard box.  
Pack sizes:  
- Box with 1 vial

#### **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.

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**

Vetpharma Animal Health, S.L

**7. MARKETING AUTHORISATION NUMBER**

Vm 32509/4001

**8. DATE OF FIRST AUTHORISATION**

25 March 2009

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

December 2024

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

Approved 01 May 2025

*Gavin Hall*