1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ANTISEDAN 5 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Atipamezole hydrochloride 5 mg/ml

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/ml
Sodium Chloride	
Water for Injection	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Elimination of the sedative and other effects of medetomidine or dexmedetomidine in dogs and cats.

3.3 Contraindications

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

Do not use in pregnant animals.

3.4 Special warnings

After administration of this veterinary medicinal product, the animals should be allowed to rest in a maximally quiet place.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This veterinary medicinal product must not be administered earlier than 30 to 40 minutes if used in patients administered ketamine with medetomidine or dexmedetomidine. If the effect of the alpha-2 agonist is eliminated earlier, the residual effect of ketamine may cause convulsions.

Care must be taken when treating animals with known liver disease.

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

Contact with the skin or mucous membranes should be avoided and impervious gloves should be worn during administration. If contamination occurs, the skin or the mucosal surface should be immediately rinsed with water.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Drowsiness[1]
Very rare (<1 animal/10,000 animals treated, including isolated reports):	Vomiting, Involuntary defecation, Increased salivation. Panting Muscle tremor, shivering. Hyperactivity[2] Tachycardia[2] Polyuria Hypotension[3]

[1] Following recovery.
[2] Rapidly transient.
[3] In dogs only, transient effect observed during the first ten minutes post-injection.

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 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 and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. The use is not recommended during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

No harmful interactions with other agents have been encountered in clinical trials, however concurrent use of those drugs affecting the CNS is not recommended apart from those mentioned in section 3.9.

3.9 Administration routes and dosage

For single intramuscular injection. Atipamezole is administered 15 to 60 min. after medetomidine or dexmedetomidine. The recovery time for dogs and cats is shortened to approximately 5 minutes. The animals become mobile approximately 10 minutes after administration of the product.

Dogs: The optimal dose of atipamezole-HCl in micrograms per kilogram is five times that of the previous medetomidine-HCl dose, or 10 times the dexmedetomidine-HCl dose. Thus in dogs an equal

volume of Antisedan to that of the previously administered Domitor (1 mg medetomidine-HCl per ml) or Dexdomitor (0.5 mg dexmedetomidine-HCl per ml) should be given. The Antisedan dose in millilitres is one fifth (1/5) of the administered dose volume of Dexdomitor (0.1 mg dexmedetomidine-HCl per ml).

Cats: The optimal dose of atipamezole-HCl, in micrograms per kg is two-and-a-half times that of the previous medetomidine-HCl dose, or five times the dexmedetomidine-HCl dose. Thus in cats half the volume of Antisedan to that of the previously administered Domitor (1 mg medetomidine-HCl per ml) or Dexdomitor (0.5 mg dexmedetomidine-HCl per ml) should be given. The Antisedan dose in millilitres is one tenth (1/10) of the administered dose volume of Dexdomitor (0.1 mg dexmedetomidine-HCl per ml).

Example dosages:

Dogs:

Domitor (1 mg/ml)	Dexdomitor (0.5 mg/ml)	Dexdomitor (0.1 mg/ml)	Antisedan (5 mg/ml)
40 mcg/kg = 1000 mcg/m^2	20 mcg/kg = 500 mcg/m^2	20 mcg/kg = 500 mcg/m^2	200 mcg/kg = 5000 mcg/m^2
0.4 ml/10 kg	0.4 ml/10 kg	2.0 ml/10 kg	0.4 ml/10 kg

Cats:

Domitor (1 mg/ml)	Dexdomitor (0.5 mg/ml)	Dexmedomitor (0.1 mg/ml)	Antisedan (5 mg/ml)
80 mcg/kg	40 mcg/kg	40 mcg/kg	200 mcg/kg
0.4 ml/5 kg	0.4 ml/5 kg	1.0 ml/3 kg*	0.2 ml/ 5 kg 0.1 ml/3 kg

*For cats weighing over 3 kg dexmedetomidine 0.5 mg/ml is recommended.

Additionally, this veterinary medicinal product can be used for reversal when the animal has been sedated with the combination of ketamine and medetomidine or dexmedetomidine. The veterinary medicinal product dosage in this instance is the same as that used for recovery after single administration of medetomidine or dexmedetomidine; however, the veterinary medicinal product should not be administered prior to 30 to 40 min. following ketamine administration.

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

Overdose is manifested as reversible hyperactivity and tachycardia. These signs are usually mild and self-limited within a couple of hours and thus do not usually warrant therapy.

Over-alertness in the cat is best handled by minimising external stimuli.

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.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QV03AB90

4.2 Pharmacodynamics

Atipamezole is a potent and selective alpha-2 adrenoceptor blocking agent (alpha-2 adrenergic antagonist), which promotes release of noradrenaline both in the central and peripheral nervous systems. This leads to activation of the central nervous system secondary to sympathetic activation.

As an alpha-2 antagonist, atipamezole is capable of eliminating (or inhibiting) the effects of the alpha-2 adrenoceptor agonist, medetomidine or dexmedetomidine. Thus, atipamezole rapidly reverses the effects of medetomidine or dexmedetomidine in dogs and cats and permits the animal to return to normal (e.g. the animals regain consciousness and become ambulatory).

4.3 Pharmacokinetics

Atipamezole is rapidly absorbed after intramuscular injection. The peak concentration in the central nervous system is reached in 10 to 15 minutes. The distribution volume (V_d) is 1 to 2.5 L/kg after IM administration.

The half-life of atipamezole in the dog is approximately 1 hour. Atipamezole is oxidised mainly in the liver; a small proportion is methylated in the kidneys. The metabolites are primarily excreted in the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

No harmful interactions with other agents have been encountered in clinical trials, however concurrent use of drugs affecting the CNS is not recommended, apart from those in the data sheet.

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 store above 25°C.
Protect from light.

5.4 Nature and composition of immediate packaging

Colourless glass type I vial with bromobutyl rubber stopper containing 10 ml.

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

Orion Corporation

7. MARKETING AUTHORISATION NUMBER(S)

VPA10664/003/001

8. DATE OF FIRST AUTHORISATION

26/02/2010

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

24/06/2024

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).