SUMMARY OF PRODUCT CHARACTERISTICS

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

Excipient:
Methyl parahydroxybenzoate (E 218) 1 mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Atipamezole is indicated for the reversal of the sedative & analgesic effects of medetomidine or dexmedetomidine in dogs and cats. It also reverses all other effects of medetomidine or dexmedetomidine, such as cardiovascular and respiratory effects.

4.3 Contraindications

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

4.4 Special warnings for each target species

After administration of this veterinary medicinal product, the animals should be allowed to rest in a maximally quiet place.
When any combination of butorphanol or medetomidine or dexmedetomidine and ketamine have been used, atipamezole should not be used to reverse the effect in dogs.

4.5 Special precautions for use

Special precautions for use in animals

of those drugs mentioned within the SPC, the concurrent use of CNS is not recommended.

Antisedan should not be administered within 30-40 minutes of the administration of ketamine in cats. If the effect of the alpha-2 agonist is eliminated earlier, the residual effect of ketamine may cause convulsions.

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

Due to the potent pharmacological activity of atipamezole, contact with skin or mucosal membranes should be avoided and impervious gloves should be worn during administration. Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek immediate medical attention showing a copy of the package leaflet. Do not drive. The patient should not be left unattended. In case of accidental spillage, wash the affected area immediately with clean running water. Seek medical attention if irritation persists. In case of accidental ingestion, seek medical advice immediately.

4.6 Adverse reactions (frequency and seriousness)

Adverse reactions are very rare.

In dogs a transient hypotensive effect has been observed during the first ten minutes post-injection. Vomiting, panting, defaecation and excessive salivation and muscle tremors (possibly shivering) have been reported but these effects appear to be very rare. Transient hyperactivity and tachycardia may be observed in a few individuals. In cats, when using low doses to partially reverse the effects of medetomidine or dexmedetomidine, the possibility of hypothermia (even when aroused from sedation) should be guarded against.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

No harmful interactions have been identified in clinical trials, however concurrent use of those drugs affecting the CNS is not recommended apart from those in the SPC

4.9 Amounts to be administered and administration route

For intramuscular injection.
Dogs: The optimal dose of atipamezole in micrograms per kilogram is five times that of the previous medetomidine dose or 10 times the dexmedetomidine dose.
millilitres is the same as that of medetomidine 1 mg/ml or
).5 mg/ml dose. Antisedan dose in millilitres is one fifth (1/5) of the

dose volume of dexmedetomidine 0.1 mg/ml. When medetomidine or dexmedetomidine have been used with or without butorphanol as a premedicant to thiopentone-halothane anaesthesia in dogs, or as premedicant to propofol anaesthesia in dogs, the product may be administered in the post-operative phase to reverse the effects of medetomidine or dexmedetomidine and hasten recovery.

Cats: The optimal dose of atipamezole in micrograms per kg is two-and-a-half times that of the previous medetomidine dose or five times the dexmedetomidine dose. The Antisedan dose in millilitres is half of that of medetomidine 1 mg/ml or dexmedetomidine 0.5 mg/ml dose and one tenth (1/10) of dexmedetomidine 0.1 mg/ml dose.

Example dosages:

Dogs:

Medetomidine dosage	Dexmedetomidine 0.5 mg/ml dosage	Dexmedetomidine 0.1 mg/ml dosage	Antisedan dosage
40 mcg/kg	20 mcg/kg	20 mcg /kg	200 mcg/kg
= 0.4 ml/10 kg	= 0.4 ml/10 kg	= 2.0 ml/10 kg	= 0.4 ml/10 kg

Cats:

Medetomidine dosage	Dexmedetomidine 0.5 mg/ml dosage	Dexmedetomidine 0.1 mg/ml dosage	Antisedan dosage
80 mcg/kg	40 mcg/kg	40 mcg/kg	200 mcg/kg
= 0.4 ml/5 kg	= 0.4 ml/5 kg	= 1.2 ml/3 kg*	= 0.2 ml/5kg 0.12 ml/3kg

* For cats weighing over 3 kg, dexmedetomidine 0.5 mg/ml is recommended.
The dose in micrograms per kg should not exceed four times that of the previously administered medetomidine or eight times that of dexmedetomidine.
When cats have been anaesthetised with medetomidine or dexmedetomidine, with or without butorphanol, and ketamine the product may be administered to reverse the effects of medetomidine or dexmedetomidine and so speed recovery from anaesthesia. 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 minutes following ketamine administration.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Transient over-alertness and tachycardia may be observed after a possible over-dosage.

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antidotes, atipamezole
ATCvet code: QV03AB90

Atipamezole is a selective α-2 adrenoceptor antagonist which is capable of reversing the sedative and analgesic effects of medetomidine or dexmedetomidine in dogs and cats. It also reverses all other effects of medetomidine or dexmedetomidine, such as cardiovascular and respiratory effects.
Atipamezole is quickly absorbed and is generally administered 15 - 60 minutes after the medetomidine or dexmedetomidine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E 218)
Sodium chloride
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose, use the product within 3 months. Discard any unused material.

6.5 Nature and composition of immediate packaging

Colourless glass type I vial containing 10 ml.
Glass (Type I) injection vial of 10 ml with grey bromobutyl rubber stopper with a fluorinated polymer coating.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

8. MARKETING AUTHORISATION NUMBER

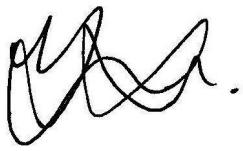
Vm 06043/4004

9. DATE OF FIRST AUTHORISATION

26 September 1989

10. DATE OF REVISION OF THE TEXT

August 2019



Approved: 03 September 2019