Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Antisedan 5 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substance:

Atipamezole (as atipamezole hydrochloride)	5 mg

Excipients:

Methyl parahydroxybenzoate (E 218)	1 mg

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

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

4.3 Contraindications

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

Do not use in pregnant animals (see section 4.7).

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.

4.5 Special precautions for use

Special precautions for use in animals

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.

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, excessive salivation panting, defecation and muscle tremors (possibly shivering) have been reported but these symptoms are very rare. An increase in diuresis may occur.
Rapidly transient hyperactivity and tachycardia may be observed in a few individuals.

In rare cases, following recovery animals may become drowsy again.

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 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 4.9.

4.9 Amounts to be administered and administration route

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)	Dexdomitor (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.

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

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.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antidote, alpha-2 adrenoceptor antagonist.
ATC vet Code: QV03AB90.

5.1 Pharmacodynamic properties

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).

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenxzoate (E 218)
Sodium Chloride
Water for Injection

6.2 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.

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: 28 days.
Dispose of any unused material as described in 6.6.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10664/003/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd February 2010

10 DATE OF REVISION OF THE TEXT

December 2016