PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Antisedan 5 mg/ml Solution for injection
Atipamezole hydrochloride 5 mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of solution contains:
Atipamezole hydrochloride 5 mg and
1 mg methylparahydroxybenzoate as antimicrobial preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dog, cat

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

-

10. EXPIRY DATE

EXP:
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.
Following withdrawal of the first dose, use the product within 3 months.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

To be supplied only on veterinary prescription.

UK Authorised Veterinary Medicinal Product

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Distributed by:
VETOQUINOL UK LIMITED
Pury Hill Business Park
Towcester
Northants
NN12 7LS

Marketing authorisation holder:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Orion-logo
Vétoquinol -logo

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06043/4004

POM-V

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Antisedan 5 mg/ml Solution for injection
Atipamezole hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

5 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

IM

See package leaflet for full instructions, operator warnings and disposal advice.

5. WITHDRAWAL PERIOD

-

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

Following withdrawal of the first dose use the product within 3 months.

POM-V

Orion logo

PACKAGE LEAFLET FOR:
Antisedan 5 mg/ml solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Antisedan 5 mg/ml solution for injection
Atipamezole hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substance:
Atipamezole hydrochloride 5 mg/ml

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

Clear colourless solution.

4. INDICATIONS

Atipamezole is a selective alpha-2 adrenergic receptor 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 the cardiovascular and respiratory effects.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Adverse reactions are very rare.

In dogs a transient hypotensive effect has been observed during the first ten minutes post-injection. Vomiting, panting, defaecation, 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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For intramuscular injection.

Dogs:
The optimal dose of atipamezole in micrograms per kilogram (mcg/kg) is 5 times that of the previous medetomidine dose or 10 times that of the previous dexmedetomidine dose. Antisedan dose in millilitres is the same as that of medetomidine 1 mg/ml or dexmedetomidine 0.5 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 kilogram (mcg/kg) is 2.5 times that of the previous medetomidine dose or 5 times that of the previous 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.

The dose of Antisedan, in micrograms per kilogram (mcg/kg), should not exceed 4 times that of the previously administered medetomidine or 8 times that of dexmedetomidine.

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.

When cats have been anaesthetised with medetomidine or dexmedetomidine, with or without butorphanol, and ketamine, Antisedan 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.

9. ADVICE ON CORRECT ADMINISTRATION

Please see section 8.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.
Following withdrawal of the first dose use the product within 3 months.
Discard any unused material.
Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP: MM/YY. The expiry date refers to the last day of that month.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in

the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNINGS

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.

Special precautions for use in animals:
With the exception of those drugs mentioned within the SPC, the concurrent use of drugs affecting the 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 and 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 this product literature. 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.

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.

Interaction with other medicinal products and other forms of interaction:
No harmful interactions have been identified in clinical trials, however concurrent use of drugs affecting the CNS is not recommended apart from those in this leaflet.

Overdose (symptoms, emergency procedures, antidotes):
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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2018

15. OTHER INFORMATION

FOR ANIMAL TREATMENT ONLY

LEGAL CATEGORY
POM-V
To be supplied only on veterinary prescription
UK Authorised Veterinary Medicinal Product

PACKAGE QUANTITIES
Antisedan is provided in 10 ml vials.

MARKETING AUTHORISATION NUMBER
Vm 06043/4004

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER:

Orion Corporation
Orionintie 1
FI- 02200 Espoo
Finland

Distributed by:
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