*The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it.*

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Antisedan Veterinary

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

Atipamezole hydrochloride 5 mg/ml

For a full list of excipients, see Section 6.1.

## 3. PHARMACEUTICAL FORM

Clear and colourless solution for Injection.

## 4. CLINICAL PARTICULARS

### 4.1 Target Species

Dogs and Cats.

### 4.2 Indications for Use, Specifying the Target Species

Elimination of the sedative effects of medetomidine in dogs and cats.

See section 4.4 for restrictions.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

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

i. Special precaution(s) 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.

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

Due to the potent pharmacological activity of atipamezole, skin contact with this product 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)

In dogs a transient hypotensive effect has been observed during the first ten minutes post-injection. Vomiting, panting, defaecation and muscle tremors (possibly shivering) have been reported, but these effects appear to be rare.

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.

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il

### 4.7 Use during pregnancy, lactation or lay

The product has only been administered to a limited number of pregnant dogs and cats and therefore cannot be recommended in pregnancy.

### 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/S.C. injection.

Dogs: The optimal dose in micrograms per kilogram is five times that of the previous medetomidine dose. The Antisedan dose in millilitres is the same as that of medetomidine. When

medetomidine has been used as a premedicant to 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.

In the post-operative phases the product rapidly causes arousal to full awareness and thus radically reduces the period of possible cardiovascular depression and hypothermia.

Cats: The optimal dose of the product, in micrograms per kg is two-and-a-half times that of the previous medetomidine dose. The Antisedan dose in millilitres is half of that of medetomidine.

The dose in micrograms per kg should not exceed four times that of the previously administered medetomidine.

When cats have been anaesthetised with medetomidine and ketamine, the product may be administered to reverse the effects of medetomidine and so speed recovery from anaesthesia.

**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

Atipamezole is a selective α-2 adrenoceptor antagonist which is capable of reversing the sedative and analgesic effects of medetomidine in dogs and cats. It also reverses all other effects of medetomidine, such as cardiovascular and respiratory effects.

Atipamezole is quickly absorbed and is generally administered 15 - 60 minutes after the medetomidine.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Methyl Parahydroxybenzoate
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

Do not use the veterinary medicinal product after the expiry date (**exp. Date**) mentioned on the package. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 28 days.

### 6.4 Special Precautions for Storage

Store below 25°C.

Protect from light.

Following withdrawal of the first dose, use the product within 28 days.

### 6.5 Nature and composition of immediate packaging

Glass type I vial containing 10 ml.

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

Any unused veterinary medicinal product or waste materials from such veterinary medicinal products should be disposed of as a toxic waste. Do not dispose of in the sewage system.

## 7. MARKETING AUTHORISATION HOLDER

Zoetis Israel Holding B.V.
5 Atir Yeda Street, Kfar Saba, Israel

## 8. MARKETING AUTHORISATION NUMBER(S)

141-85-92305-01

## 9. MANUFACTURER

Orion Corporation Orion Pharma, Finland
Espoo Plant
Orionintie 1
FIN-02200 Espoo
Finland

## 10. VETERINARY USE

The veterinary medicine is dispensed with a veterinarian's prescription only.

zoetis