SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormostop 5 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contains:

Active substance:

Atipamezole hydrochloride (equivalent to 4.27 mg atipamezole)	5.0 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

Reversal of the sedative effects of medetomidine and dexmedetomidine.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals suffering from hepatic or renal diseases.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i)Special precautions for use in animals
After administration of the product, the animals should be allowed to rest in a quiet place.

If sedatives other than (dex)medetomidine are given, it must be kept in mind that the effects of those other agents may persist after reversal of (dex)medetomidine.
Atipamezole does not reverse the effect of ketamine, which may cause seizures in dogs and elicit cramps in cats when used alone. Do not administer atipamezole within 30 – 40 minutes of prior administration of ketamine.

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

This product may cause irritation to the skin, eyes and mucous membranes. Dermal and ocular exposure should therefore be avoided. In case of accidental dermal or ocular exposure, rinse the skin and/or the eye with water. Seek medical attention if irritation persists and show the package leaflet to the physician.

This product causes adrenergic effects. Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Hyperactivity, tachycardia, increased salivation, atypical vocalisation, muscle tremor, vomiting, increased respiratory rate, uncontrolled urination and uncontrolled defecation.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Recurrence of sedation may occur or the recovery time may not be shortened after administration of atipamezole.

A transient hypotensive effect has been observed during the first 10 minutes post injection of atipamezole hydrochloride.

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.

4.7 Use during pregnancy, lactation or lay

The safety of the product has not been established during pregnancy and lactation. Therefore the use is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

A simultaneous administration of atipamezole with other centrally acting medicinal products as diazepam, acepromazine or opiates is not recommended.

4.9 Amount(s) to be administered and administration route

For single intramuscular injection.
Atipamezole hydrochloride is administered 15-60 min after medetomidine or dexmedetomidine hydrochloride administration.

Dogs: the intramuscular atipamezole hydrochloride dose [in µg] is five times that of the previous medetomidine hydrochloride dose or ten times that of the dexmedetomidine hydrochloride dose. Due to the 5-fold higher concentration of the active ingredient (atipamezole hydrochloride) in this product compared to that of preparations containing 1 mg medetomidine hydrochloride per ml and the 10-fold higher concentration compared to that of preparations containing 0.5 mg dexmedetomidine hydrochloride, an equal volume of each preparation is required.

Dosage example dogs:

Dose **Medetomidine** **1 mg/ml**	**Dose** **Dexmedetomidine** **0,5 mg/ml**	**Dose** **Atipamezole** **5 mg/ml**
1000 mcg/m2 40 mcg/kg	500 mcg/m2 20 mcg/kg	5000 mcg/m2 200 mcg/kg
= 0.04 ml/kg	= 0.04 ml/kg	= 0.04 ml/kg

Cats: the intramuscular atipamezole hydrochloride dose [in µg] is two-and-a-half times that of the previous medetomidine hydrochloride dose or five times that of the dexmedetomidine hydrochloride dose. Due to the 5-fold higher concentration of the active ingredient (atipamezole hydrochloride) in this product compared to that of preparations containing 1 mg medetomidine hydrochloride per ml and the 10-fold higher concentration compared to that of preparations containing 0.5 mg dexmedetomidine hydrochloride, half the volume of the product to that of the previously administered medetomidine or dexmedetomidine should be given.

Dosage example cats:

Dose Medetomidine 1 mg/ml	Dose Dexmedetomidine 0,5 mg/ml	Dose Atipamezole 5 mg/ml
80 mcg/kg	40 mcg/kg	200 mcg/kg
= 0.08 ml/kg	= 0.08 ml/kg	= 0.04 ml/kg

The recovery time is shortened to approximately 5 minutes. The animals become mobile after approximately 10 minutes after administration of the product.

The stoppers should not be broached more than 30 times.

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

Overdose of atipamezole hydrochloride may result in transient tachycardia and over-alertness (hyperactivity, muscle tremor). If necessary, these symptoms may be reversed by a (dex)medetomidine hydrochloride dose which is lower than the usually used clinical dose.
If atipamezole hydrochloride is inadvertently administered to an animal not previously treated with (dex)medetomidine hydrochloride, hyperactivity and muscle tremor may occur. These effects may persist for about 15 minutes. 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

ATC Vet Code: QV03AB90

5.1 Pharmacodynamic properties

Atipamezole is a potent and selective α2-receptor blocking agent (α2-antagonist), which promotes the release of the neurotransmitter noradrenaline in the central as well as in the peripheral nervous systems. This leads to activation of the central nervous system due to sympathetic activation. Other pharmacodynamic effects as for example influence of the cardiovascular system are only mild – but a transient decrease of blood pressure may be seen within the first 10 minutes after injection of atipamezole hydrochloride.
As a α2-antagonist, atipamezole is capable of eliminating (or inhibiting) the effects of the α2-receptor agonist, medetomidine or dexmedetomidine. Thus atipamezole reverses the sedative effects of (dex)medetomidine hydrochloride in dogs and cats to normal and may lead to a transient increase in heart rate.

5.2 Pharmacokinetic particulars

Atipamezole hydrochloride is rapidly absorbed after intramuscular injection. The maximal concentration in the central nervous system is reached in 10-15 minutes. Volume of distribution (Vd) is about 1 – 2.5 l/kg. The half-life (t½) of atipamezole hydrochloride is reported to be approximately 1 hour. Atipamezole hydrochloride is rapidly and completely metabolised. The metabolites are mainly excreted in urine and in a small amount in faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Sodium chloride
Hydrochloric acid, diluted (for pH-adjustment)
Sodium hydroxide (for pH-adjustment)
Water for injections

6.2 Major 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: 30 months
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Cardboard box with a clear/white glass (Type I) vial of 10 ml, containing 5 ml or 10 ml product, or 20 ml, containing 20 ml product, with a coated bromobutyl rubber stopper and aluminium cap.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

8. MARKETING AUTHORISATION NUMBER

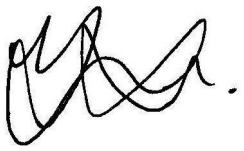
Vm 36408/5018

9. DATE OF FIRST AUTHORISATION

18 September 2023

10. DATE OF REVISION OF THE TEXT

September 2023



Approved: 18 September 2023