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

Each ml contains:

Active substance:
Atipamezole 4.27 mg
(equivalent to 5.0 mg atipamezole hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate (E218)	1.0 mg
Sodium chloride	
Hydrochloric acid, diluted (for pH-adjustment)	
Sodium hydroxide (for pH-adjustment)	
Water for injections	

Clear colourless, practically free from particles solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats

3.2 Indications for use for each target species

Reversal of the sedative effects of medetomidine and dexmedetomidine.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
After administration of the veterinary medicinal product, the animals should be allowed to rest in a quiet place.
Atipamezole reverses all effects of (dex)medetomidine, thus the sedative, analgesic and cardiovascular effects which may lead to a transient increase in heart rate.
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal 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 or the label to the physician.
This veterinary medicinal product may cause 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 or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Hyperactivity; Tachycardia, arrhythmias; Increased salivation, vomiting, diarrhoea, and involuntary defecation; Atypical vocalisation; Muscle tremor; Increased respiratory rate; Uncontrolled micturition.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Sedation[1].
Undetermined (frequency cannot be estimated from the available data)	Hypotension[2].

[1] Recurrence of sedation may occur or the recovery time may not be shortened.
[2] Transient, during the first 10 minutes post injection of atipamezole hydrochloride.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

For single intramuscular use.
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 veterinary medicinal product compared to that of veterinary medicinal products containing 1 mg medetomidine hydrochloride per ml and the 10-fold higher concentration compared to that of veterinary medicinal products containing 0.5 mg dexmedetomidine hydrochloride, an equal volume of each veterinary medicinal product is required.
The concentration of atipamezole hydrochloride in the veterinary medicinal product being 50-fold higher compared to that of veterinary medicinal products containing 0.1 mg/ml dexmedetomidine hydrochloride, the volume of the veterinary medicinal product that is required is 5-fold lower than of the solution of dexmedetomidine hydrochloride.

Dosage example dogs:

Dose Medetomidine HCl 1 mg/ml	**Dose Dexmedetomidine HCl 0.5 mg/ml**	**Dose Dexmedetomidine HCl 0.1 mg/ml**	**Dose Atipamezole HCl 5 mg/ml**
40 µg/kg	20 µg/kg	20 µg/kg	200 µg/kg
= 0.04 ml/kg	= 0.04 ml/kg	= 0.2 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 veterinary medicinal product

compared to that of veterinary medicinal products containing 1 mg medetomidine hydrochloride per ml and the 10-fold higher concentration compared to that of veterinary medicinal products containing 0.5 mg dexmedetomidine hydrochloride, half the volume of the veterinary medicinal product to that of the previously administered medetomidine or dexmedetomidine should be given.
The concentration of atipamezole hydrochloride in the veterinary medicinal product being 50-fold higher compared to that of veterinary medicinal products containing 0.1 mg/ml dexmedetomidine hydrochloride, the volume of the veterinary medicinal product that is required is 10-fold lower than of the solution of dexmedetomidine hydrochloride.

Dosage example cats:

Dose Medetomidine HCl 1 mg/ml	**Dose Dexmedetomidine HCl 0.5 mg/ml**	**Dose Dexmedetomidine HCl 0.1 mg/ml**	**Dose Atipamezole HCl 5 mg/ml**
80 µg/kg	40 µg/kg	40 µg/kg	200 µg/kg
= 0.08 ml/kg	= 0.08 ml/kg	= 0.4 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 veterinary medicinal product.

Do not exceed a maximum of 1 ml per injection site. The dose to be administered should preferably be divided over 2 injection sites.
The stoppers should not be broached more than 30 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration only by a veterinarian.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QV03AB90

4.2 Pharmacodynamics

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 on for example the cardiovascular system are only mild. As a α2-antagonist, atipamezole is capable of eliminating (or inhibiting) the effects of the α2-receptor agonist, medetomidine or dexmedetomidine.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Cardboard box with a type I clear glass vial of 10 ml, or 20 ml, with a coated bromobutyl rubber stopper and aluminium cap.

Pack sizes:
5 ml (in a 10 ml sized vial)
10 ml
20 ml

Not all pack sizes may be marketed.

5.5 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 or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 36408/5018

8. DATE OF FIRST AUTHORISATION

18 September 2023

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

September 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 21 October 2025