ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormostop 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

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

3. PACKAGE SIZE

5 ml
10 ml
20 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/3022

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials of 5 mL (in a 10 mL vial)
Glass vials of 10 mL
Glass vials of 20 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormostop

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

4.27 mg/ml atipamezole
(equivalent to 5.0 mg atipamezole hydrochloride)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

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

Excipients:
Methyl parahydroxybenzoate (E218) 1 mg

Clear colourless, practically free from particles solution

3. Target species

Dog, cat

4. Indications for use

Reversal of the sedative effects of medetomidine and dexmedetomidine.

5. 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.

6. Special warnings

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 to the physician.
This veterinary medicinal product may cause adrenergic effects. Care should be taken to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician.

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.

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.

Overdose:
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.

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

7. Adverse events

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Hyperactivity. Tachycardia, arrhythmias. Increased salivation, vomiting, diarrhoea, 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	Hypotension[2]

(frequency cannot be estimated from the available data)	

[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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder, using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

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 broached more than 30 times.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

This veterinary medicinal product does not require any special storage conditions.
Shelf life after first opening the immediate packaging: 28 days
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Cardboard box with type I clear glass vial of 10 ml or 20 ml with 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.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

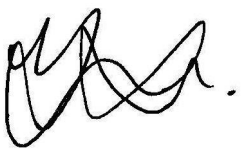
Detailed information on this veterinary medicinal product is available in the Union Product Database.
(https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

17. Other information



Approved: 26 July 2023