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 AND OTHER SUBSTANCES

1 ml solution contains:

Active substance:

Atipamezole hydrochloride 5.0 mg

(equivalent to 4.27 mg atipamezole)

3. PACKAGE SIZE

5 ml
10 ml
20 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

IM

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.

Once broached, use by:

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/5018

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V ('To be supplied only on veterinary prescription')

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {10 or 20 ml vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormostop 5 mg/ml solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1 ml solution contains:

Active substance:

Atipamezole hydrochloride 5.0 mg

(equivalent to 4.27 mg atipamezole)

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.

Once broached, use by:

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

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. 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

Clear, colourless solution.

3. TARGET SPECIES

Dogs and cats

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 WARNING(S)

For Animal Treatment Only.

Special precautions for safe use in the target species:

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.

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.

Pregnancy and lactation:

The safety of the product has not been established during pregnancy and lactation. Therefore 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, 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.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

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

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 container should be discarded should be determined. This discard date should be written in the space provided on the label.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

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.

Vm 36408/5018

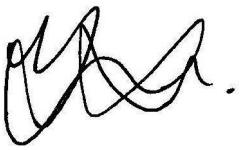
15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

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

16. CONTACT DETAILS

To include: Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different.

17. OTHER INFORMATION



Approved: 18 September 2023