PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormostart 1 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substances:
Medetomidine hydrochloride……..…1.0 mg
(equivalent to 0.85 mg of medetomidine)

Excipients:
Methyl parahydroxybenzoate (E218) ..... 1.0 mg
Propyl parahydroxybenzoate ..... 0.2 mg

3. PACKAGE SIZE

5 ml
10 ml
20 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

IM, SC, IV

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 28 days.

Once opened 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 OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/5021

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Alpha 2-adrenoreceptor agonists can cause severe adverse reactions. You must read the warnings on the package leaflet before using this product.

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V - To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {GLASS VIAL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormostart 

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Medetomidine hydrochloride 1.0 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

Once opened use within 28 days.

Once opened used by….

5. ROUTE(S) OF ADMINISTRATION

IM, SC, IV

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormostart 1 mg/ml solution for injection for dogs and cats

2. COMPOSITION

Each ml contains:
Active substances:

Medetomidine hydrochloride……..…1.0 mg
(equivalent to 0.85 mg of medetomidine)

Excipients:
Methyl parahydroxybenzoate (E218) ..... 1.0 mg
Propyl parahydroxybenzoate ..... 0.2 mg

Solution for Injection
Clear, colourless solution.

3. TARGET SPECIES

Dogs and cats

4. INDICATIONS FOR USE

Dogs: For restraint, sedation and analgesia associated with clinical examinations and procedures, minor surgery and as premedication prior to general anaesthesia.

In combination with butorphanol for sedation and analgesia.

Cats: For restraint and sedation.
In combination with ketamine for the induction of general anaesthesia prior to surgical procedures

In combination with butorphanol for sedation and analgesia, and combined with both butorphanol and ketamine for general anaesthesia.

5. CONTRAINDICATIONS

Do not use in animals with heart failure, respiratory disease or impaired liver or kidney function, animals in shock, seriously debilitated animals, or animals that are stressed due extreme heat, cold or fatigue.
Do not use in conjunction with sympathomimetic amines.
Do not use in dogs under 12 weeks of age.

6. SPECIAL WARNINGS

Special warnings for each target species
When medetomidine is administered, the animal should be allowed to rest in a maximally quiet place. Before any procedure is started or other drugs are administered, sedation should be allowed to reach its peak effect, which occurs at about 10 to 30 min, depending on route of administration.
In extremely nervous, excited or agitated animals, the levels of endogenous catecholamines may be high. The pharmacological response elicited by alpha-2 agonists (e.g. medetomidine) in such animals is often reduced, with depth and duration of sedative and analgesic effects ranging from slightly diminished to non-existent. Highly agitated animals should therefore be put at ease and allowed to rest quietly prior to receiving medetomidine. Allowing animals to rest quietly for 10 to 15 minutes after injection may improve the response to medetomidine.

Special precautions for use in animals
A clinical examination should be carried out in all animals before the use of drugs for sedation and/or general anaesthesia.
Care should be taken when using medetomidine in animals with cardiovascular disease.
Care should be taken when combining medetomidine with other anaesthetics or sedatives. Before using any combinations consult the contraindications and warnings that appear on the concomitant product's data sheet.
Medetomidine has marked anaesthetic sparing effects. The dose of the anaesthetic should be reduced accordingly (see section 4.9).
Special care is recommended when treating very young animals and older animals.
Medetomidine, ketamine and propofol are metabolised in the liver and excreted primarily via the kidneys. Pre-existing liver or kidney pathology should be carefully evaluated to confirm adequate function prior to using these products.
Fasting is recommended before medetomidine administration. After treatment, the animal should not be given water or food before it is able to swallow properly.
Treated animals should be kept in a warm and even temperature during the procedure and for 12 hours after sedation.
During prolonged procedures an ophthalmic preparation should be administered at regular intervals to lubricate the cornea especially in cats and sometimes also in dogs if their eyes remain open. In cats, when medetomidine is used in combination with ketamine, laryngeal and pharyngeal reflexes are retained during anaesthesia.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product is a sedative. Care should be taken to avoid oral intake and/or accidental self-injection.
In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the physician, but DO NOT DRIVE as sedation and changes in blood pressure may occur.
Avoid skin, eye or mucosal contact. In the case of accidental contact of the product with the skin or eyes, rinse with large amounts of fresh water. Remove contaminated

clothes that are in direct contact with skin. If symptoms occur, seek the advice of a physician.
If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.
People with known hypersensitivity to parabens should administer the veterinary medicinal product with caution.

Advice to doctors:
Medetomidine is an alpha2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported.
Respiratory and haemodynamic symptoms should be treated symptomatically.

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

Interactions with other medicinal products and other forms of interaction
Medetomidine should not be used in conjunction with sympathomimetic amines. The concomitant use of other central nervous system depressants should be expected to potentiate the effect of either product and appropriate dose adjustment should be made. Medetomidine must not be mixed with other products, with the exception of ketamine or butorphanol.

Medetomidine has marked anaesthetic sparing effects. The dose of compounds such as propofol and volatile anaesthetics should be reduced accordingly, by up to 50 - 90 %, depending on the individual animal.
Although bradycardia may be partially prevented by prior administration (at least 5 minutes before medetomidine) of an anticholinergic agent, the administration of anticholinergic agents to treat bradycardia either simultaneously with medetomidine or following sedation with medetomidine could lead to adverse cardiovascular effects.

Major incompatibilities
Medetomidine must not be mixed with other products with the exception of ketamine and butorphanol.

7. ADVERSE EVENTS

Blood pressure will increase initially and then return to normal or slightly below normal. Bradycardia with occasional atrioventricular block may occur. Cyanosis has been reported.
Some dogs and most cats vomit 5 to 15 minutes after injection. Some cats may also vomit upon recovery.
Body temperature is slightly or moderately decreased and prolonged recovery may lead to hypothermia.

An increase in blood glucose concentration is seen due to alpha-2 adrenoreceptor mediated inhibition of insulin secretion.
Urination typically occurs during recovery at about 90 to 120 minutes posttreatment.

Some animals experience muscle tremors and may be sensitive to loud sounds. Incidents of prolonged sedation and recurrence of sedation after initial recovery have been reported.

Isolated cases of hypersensitivity, paradoxical response (excitation) and lack of efficacy have been reported.
Death from circulatory failure with severe congestion of the lungs, liver, or kidney has been reported. Decreased respiratory rates with or without transient apnoea may occur. If the animal has a pre-existing subclinical respiratory disease, administration of medetomidine can cause some significant respiratory depression which could predispose the animal to cardiac arrest. Pulmonary oedema has been reported.
The combination of medetomidine and ketamine is reported to elicit a pain response in some cats when administered intramuscularly. Heart rates will generally decrease to approximately 50% of pre-anaesthetic levels and in some cats very slow respiratory rates are observed (4-6 breaths per minute).

In dogs, when medetomidine is used in combination with propofol, movement of the forelegs may occur during induction of anaesthesia. In some cases at higher dosages, a decline in arterial oxygen tension may occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Intravenous, intramuscular or subcutaneous administration.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes. Administration by intramuscular (IM), intravenous (IV) and subcutaneous (SC) routes are possible. The effect is most rapid after IV administration and slowest after SC administration. The dosage is dependent on the degree of sedation and analgesia required.

Medetomidine	Dose
Dogs:	10-80 mcg/kg
Cats:	50-150 mcg/kg

For sedation, small dogs require more medetomidine per kg of bodyweight than large dogs thus the dosage per square meter of body surface could be more accurate. If this approach is used the dosage is 750 to 1000 mcg/square meter. The following table gives the dosage for dogs on the basis of body weight.

Body weight (kg) IV administration	**Injection volume (ml)**	**Body weight (kg) IM/ SC/ administration**
1.5-2.2	0.1	
2.3-3.5	0.15	1.8-2.3
3.6-5.1	0.2	2.4-3.3
5.2-6.9	0.25	3.4-4.5
7.0-9.9	0.3	4.6-6.4
10.0-14.4	0.4	6.5-9.4
14.5-19.5	0.5	9.5-12.7
19.6-25.1	0.6	12.8-16.3
25.2-31.1	0.7	16.4-20.2
31.2-37.6	0.8	20.3-24.4
37.7-44.4	0.9	24.5-28.9
44.5-55.3	1.0	29.0-36.1
55.4-71.1	1.2	36.2-46.3
71.2-88.2	1.4	46.4-57.3
88.3+	1.6	57.4-75.8
	2.0	75.9+

Anaesthesia:
Medetomidine is suitable for use as an anaesthetic premedication prior to general anaesthesia. Premedication dosing guide: Medetomidine has marked anaesthetic-sparing effects. It is essential to reduce appropriately the dose of anaesthetic induction and maintenance agents in animals that have been given the product.

Combinant	Dosage (Dogs)		Dosage (Cats)	
	Medetomidine (mcg/kg)	Combinant (mg/kg)	Medetomidine (mcg/kg)	Combinant (mg/kg)
Propofol	10-40	1-4	NA	NA
Butorphanol	10-25	0.1	50	0.4
Ketamine	NA	NA	80	2.5-7.5
Butorphanol + Ketamine	NA	NA	40-80	But: 0.1-0.4 Ket: 1.25-5.0
Alfaxalone /alfadolone	NA	NA	80	2.5-5.0

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Once broached use within 28 days.

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V - To be supplied only on veterinary prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 36408/5021

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

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

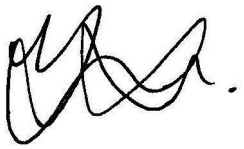
16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel: +31(0)348 416945

Local representative:

17. OTHER INFORMATION



Approved: 13 February 2024