PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

{OUTER CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domitor® 1mg/ml Solution for injection
Medetomidine hydrochloride 1 mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of solution contains:
Medetomidine hydrochloride 1 mg
Methylparahydroxybenzoate (E218) 1 mg
and propylparahydroxybenzoate 0.2 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous, intramuscular or subcutaneous injection in dogs and cats.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Consult the package leaflet for full details of use, contraindications, operator warnings and disposal advice.

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

10. EXPIRY DATE

Exp. date:
Following withdrawal of first dose use within 3 months.
White Box: Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

To be supplied only on veterinary prescription.

UK Authorised Veterinary Medicinal Product

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Distributed by:
VETOQUINOL UK LIMITED
Pury Hill Business Park
Towcester
Northants
NN12 7LS

Marketing authorisation holder:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Orion-logo
Vétoquinol-logo

16. MARKETING AUTHORISATION NUMBER

Vm 06043/4003

POM-V

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{VIAL LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domitor® 1 mg/ml solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Medetomidine hydrochloride 1 mg/ml

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch nº:

7. EXPIRY DATE

Exp. date:
Following withdrawal of first dose use within 3 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

Do not freeze.

POM-V

Orion logo

PACKAGE LEAFLET

DOMITOR® 1 mg/ml
Solution for injection

PRESENTATION
An aqueous solution, for injection, of medetomidine hydrochloride. Each ml contains medetomidine hydrochloride 1.0 mg.

Other ingredients: Methyl parahydroxybenzoate (E218) 1 mg/ml, Propyl parahydroxybenzoate 0.2 mg/ml.

USES
1. **Dogs:**
   For restraint, sedation and analgesia associated with clinical examinations and procedures, minor surgery and as premedication prior to general anesthesia.
   In combination with butorphanol for sedation and analgesia.

2. **Cats:**
   For restraint and sedation.
   In combination with ketamine for induction of general anesthesia prior to surgical procedures.
   In combination with butorphanol for sedation and analgesia, and combined with both butorphanol and ketamine for general anesthesia.
   As a premedication before alphaxalone/alphadolone for general anesthesia.

DOSAGE AND 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.

Domitor	Dose mcg/kg
Dogs	10-80
Cats	50-150

For sedation, small dogs require more Domitor 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 +

Anesthesia:
Domitor is suitable for use as an anesthetic premedication prior to general anesthesia. **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)	
	Domitor (mcg/kg)	Combinant (mg/kg)	Domitor (mcg/kg)	Combinant (mg/kg)
Propofol	10-40	1-4	NA	NA
Butorphanol	10-25	0.1	50	0.4
Ketamine			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

CONTRA-INDICATIONS

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.

SPECIAL WARNINGS

Special warnings for each target species

When Domitor 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 Domitor. Allowing animals to rest quietly for 10 to 15 minutes after injection may improve the response to Domitor.

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 anesthesia.
Care should be taken when using Domitor 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 Dosage and administration).
Special care is recommended when treating very young animals and older animals.
Domitor, 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 Domitor 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 Domitor is used in combination with ketamine, laryngeal and pharyngeal reflexes are retained during anesthesia.

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

In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation and changes in blood pressure may occur. Avoid skin, eye or mucosal contact. Immediately after exposure, wash the exposed skin with large amounts of fresh water. Remove contaminated clothes that are in direct contact with skin. In the case

of accidental contact of the product with eyes, rinse with large amounts of fresh water. If symptoms occur, seek the advice of a doctor. 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.

Advice to doctors:
Medetomidine hydrochloride is an alpha-2 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 or lactation.

Interaction 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 Vetalar and Ketaset Injection and Torbugesic injection.

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 Domitor) 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.

Overdose
Overdose is mainly manifested by delayed recovery after sedation or anesthesia. In a few individuals, circulatory and respiratory depression may occur.
The effects of Domitor can be eliminated using the specific alpha-2 adrenergic antagonist atipamezole (Antisedan). In the dog, the Antisedan dosage expressed in mcg is 5 times that of Domitor. In the cat, the Antisedan dosage expressed in mcg is 2.5 times that of Domitor.

ADVERSE REACTIONS
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 post-treatment.
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 Domitor can cause some significant respiratory depression which could predispose the animal to cardiac arrest. Pulmonary oedema has been reported.
The combination of Domitor 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-anesthetic levels and in some cats very slow respiratory rates are observed (4-6 breaths per minute).
In dogs, when Domitor is used in combination with propofol, movement of the forelegs may occur during induction of anesthesia. 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 reaction(s) 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).

PHARMACEUTICAL PRECAUTIONS
Do not freeze.
Following withdrawal of the first dose, use the product within 3 months. Discard unused material.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified above, the date on which any product remaining in the container should be discarded, should be worked out. This discard date should be written in the space provided on the carton.
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

INCOMPATIBILITIES
Medetomidine must not be mixed with other products with the exception of Vetalar and Ketaset injection and Torbugesic injection.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

FOR ANIMAL TREATMENT ONLY.

LEGAL CATEGORY POM-V

To be supplied only on veterinary prescription.
UK Authorised Veterinary Medicinal Product

PACKAGE QUANTITIES
10 ml vials.

MARKETING AUTHORISATION NUMBER:
Vm 06043/4003

DATE OF PREPARATION: June 2018

Marketing authorisation holder:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Distributed by:
VETOQUINOL UK LIMITED
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NN12 7LS

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