SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DOMITOR 1 mg/ml Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Medetomidine hydrochloride 1 mg/ml

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 (E 218)	1 mg/ml
Propyl parahydroxybenzoate	0.2 mg/ml
Sodium Chloride	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and Cats.

3.2 Indications for use for each target species

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.

As a premedicant before alfaxalone/alfadolone for general anaesthesia.

3.3 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.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 the veterinary medicinal product 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 3.9).
Special care is recommended when treating very young animals and older animals.
The veterinary medicinal product, 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 the veterinary medicinal product 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

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.

To the physician:
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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dog

Very common (>1 animal / 10 animals treated):	Bradycardia[1]
Common (1 to 10 animals / 100 animals treated):	Vomiting[2] Muscle tremor Decreased respiratory rate[3] Cyanosis
Undetermined frequency (cannot be estimated for the available data):	Excitation Heart block NOS[1] Cardiac arrest[4] High blood pressure[5] Low blood pressure[5] Hypersensitivity reaction Hyperglycaemia Recovery prolonged[6] Sedation prolonged[7] Increased sensitivity to sound Urination[8] Apnoea[3] Hypoxia[9] Pulmonary oedema Death[10] Decreased body temperature Hypothermia[6] Lack of efficacy – NOS

[1]Bradycardia with occasional atrioventricular block may occur.

[2]Some dogs vomit 5 to 15 minutes after injection.

[3]Decreased respiratory rates with or without transient apnoea periods may occur.

[4] If the animal has a pre-existing subclinical respiratory disease, administration of the veterinary medicinal product can cause significant respiratory depression which could predispose to cardiac arrest.

[5]Blood pressure will increase initially and then return to normal or slightly below normal.

[6]Prolonged recovery may lead to hypothermia.

[7]Recurrence of sedation after initial recovery has also been reported.

[8]Urination typically occurs during recovery at about 90 to 120 minutes post-treatment.

[9]In some cases at higher dosages, a decline in arterial oxygen tension may occur.

[10]Death from circulatory failure with severe congestion of the lungs, liver, or kidney has been reported.

When the veterinary medicinal product is used in combination with propofol, movement of the forelegs may occur during induction of anaesthesia.

Cat

Common (1 to 10 animals / 100 animals treated):	Vomiting[1]
Undetermined frequency (cannot be estimated for the available data):	Excitation Bradycardia[2] Heart block NOS[2] Cardiac arrest[3] High blood pressure[4] Low blood pressure[4] Hypersensitivity reaction Hyperglycaemia Recovery prolonged[5] Sedation prolonged[6] Muscle tremor Increased sensitivity to sound Urination[7] Apnoea[8] Decreased respiratory rate[8,9] Pulmonary oedema Death[10] Cyanosis Decreased body temperature Hypothermia[5] Lack of efficacy – NOS

[1]Most cats vomit 5 to 15 minutes after injection, some cats may also vomit upon recovery.

[2]Bradycardia with occasional atrioventricular block may occur.

[3]If the animal has a pre-existing subclinical respiratory disease, administration of the veterinary medicinal product can cause significant respiratory depression which could predispose to cardiac arrest.

[4]Blood pressure will increase initially and then return to normal or slightly below normal.

[5]Prolonged recovery may lead to hypothermia.

[6]Recurrence of sedation after initial recovery has also been reported.

[7]Urination typically occurs during recovery at about 90 to 120 minutes post-treatment.

[8]Decreased respiratory rates with or without transient apnoea periods may occur.

[9]In some cats very slow respiratory rates are observed (4-6 breaths per minute).

[10]Death from circulatory failure with severe congestion of the lungs, liver, or kidney has been reported. When the veterinary medicinal product is used in combination with ketamine, the combination is reported to elicit a pain response in some cats when administered intramuscularly.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to 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

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

3.8 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.

3.9 Administration routes and dosage

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 1,000 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

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

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.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

ATC vet Code: QN05CM91.
Pharmacotherapeutic group: sedative and analgesic.

4.2 Pharmacodynamics

The active ingredient of Domitor is medetomidine. Its chemical structure is 4 [1 (2,3 dimethylfenyl)ethyl] lH imidazole hydrochloride. Medetomidine is an alpha-2 adrenergic agonist with central and peripheral effects inhibiting the transmission of noradrenaline mediated nerve impulses by activating pre-and post-synaptic alpha-2 adrenoceptors. In the animal, the level of consciousness is lowered and the pain threshold is raised. The action of medetomidine is dose dependent: small doses cause mild sedation and analgesia, while larger doses produce high levels of sedation and analgesia.

Medetomidine lowers the heart rate and initially elevates the blood pressure; blood pressure returns to baseline or slightly below baseline over fifteen minutes The cardiovascular changes observed are either centrally mediated (bradycardia, hypotension) or due to direct effects on alpha-2 receptors (vasoconstriction, increased systemic vascular resistance).

The vasoconstriction may turn the mucous membranes pale or slightly bluish. Dogs may develop benign conductivity disturbances (first or second degree AV block). The respiratory rate is lowered. Local muscular twitching may occur in a few individuals. Blood glucose levels are elevated in both animal species. Body temperature decreases.

4.3 Pharmacokinetics

Medetomidine is rapidly absorbed after intramuscular injection; the t_{max} varies from 15 to 30 min. Medetomidine is also rapidly distributed in the organism. The V_d varies between 2.8 and 3.6 L/kg. Protein binding is 85 to 90%. Medetomidine is oxidised in the liver and a small proportion is methylated in the kidneys. Most metabolites are excreted in the urine. The $T_{½}$ is 1-2 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

Do not freeze.

Discard unused material.

5.4 Nature and composition of immediate packaging

Clear colourless, sterile aqueous solution and presented in clear, Type I glass vials of 10 ml capacity. Vials are fitted with a chlorobutyl rubber bung and sealed with an aluminium seal.

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.

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

Orion Corporation

7. MARKETING AUTHORISATION NUMBER

Vm 06043/4003

8. DATE OF FIRST AUTHORISATION

31 October 1988

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

December 2025

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: 18 March 2026