PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DOMOSEDAN 10 mg/ml Solution for injection
Detomidine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of solution contains:
detomidine hydrochloride 10 mg
and methyl parahydroxybenzoate (E218) 1 mg as preservative

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5 ml
20 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For i.m. or slow i.v. injection.

8. WITHDRAWAL PERIOD

Withdrawal period: meat and offal - 1 day.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Domosedan is an alpha2-adrenergic agonist.

Refer to package leaflet for use in pregnant horses.
Do not use with sympathomimetic amines.

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

10. EXPIRY DATE

EXP
Shelf life after first opening the container: 3 months.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.
Do not refrigerate or freeze. Keep the vials in the outer carton.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

–logo

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

Orion Pharma -logo

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06043/4002

17. MANUFACTURER'S BATCH NUMBER

Batch:

POM-V

PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGING UNITS LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domosedan 10 mg/ml Solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Detomidine hydrochloride 10 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5 ml
20 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

Horses (meat and offal): 1 Day

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Shelf life after first opening the container: 3 months.
Once broached use by:

11. SPECIAL STORAGE CONDITIONS

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.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Orion Pharma –logo Vetoquinol logo

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06043/4002

17. MANUFACTURER'S BATCH NUMBER

Batch n°:

POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
DOMOSEDAN® 10 mg/ml Solution for injection
Horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Orion Corporation
Orionintie 1
02200 Espoo
Finland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DOMOSEDAN® 10 mg/ml Solution for injection
Detomidine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

A clear, colourless solution for injection. Contains detomidine hydrochloride 10 mg/ml.
Other ingredients: Methyl parahydroxybenzoate (E218) 1 mg/ml.

4. INDICATION(S)

DOMOSEDAN® is a sedative with analgesic properties used with or without butorphanol to facilitate the handling of horses for examination, minor surgical interventions and other manipulations.
DOMOSEDAN® is also indicated for use with ketamine for short duration general anaesthesia to carry out surgical procedures such as castration.

5. CONTRAINDICATIONS

Before using any combinations consult the contraindications and warnings that appear on the other products' data sheets.

The use of DOMOSEDAN® in conjunction with sympathomimetic amines is contra-indicated.
Do not administer to horses in the last month of pregnancy
Do not use in seriously ill animals with heart failure or impaired liver or kidney function.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

DOMOSEDAN®: The use of DOMOSEDAN® in conjunction with sympathomimetic amines is contra-indicated.
DOMOSEDAN® should not be used in horses with pre-existing AV blocks, with severe cardiac insufficiency, respiratory disease or chronic renal failure.
Careful consideration should be given prior to administration to animals in shock and to animals with liver or kidney disease.

DOMOSEDAN® and ketamine: Do not administer simultaneously with ketamine in the same syringe (see sections Further information and Dosage and administration). Excitable horses are sometimes poor subjects for anaesthesia. It is a prime requisite that the horse should be quietly and carefully handled during the administration of the anaesthetic agents so as to ensure the minimum amount of upset during the induction period. If the horse fails to become sedated following the injection of DOMOSEDAN, then ketamine should not be injected and the anaesthetic procedure should be abandoned.

DOMOSEDAN®/butorphanol combination: The combination should not be used in pregnant animals nor in animals suffering from colic.

Routine cardiac auscultation should be performed prior to use of this combination.

Mild to severe ataxia may be encountered but clinical studies have shown that horses are unlikely to collapse. Normal precautions should be observed to prevent patient self-injury.

6. ADVERSE REACTIONS

Adverse reactions are very rare.
All alpha-2 adrenoceptor agonists, including detomidine, may cause decreased heart rate, changes in the conductivity of cardiac muscle (as evidenced by partial atrioventricular and sinoatrial blocks), changes in the respiratory rate, incoordination/ataxia and sweating.
A diuretic effect is usually observed within 45 to 60 minutes after treatment.
The potential for isolated cases of hypersensitivity exists, including paradoxical response (excitation).
Partial, transient penis prolapse may occur in male horses. In rare cases, horses may show signs of mild colic following administration of alpha-2 adrenoceptor agonists because substances of this class inhibit intestinal motility.
Occasional reports of urticaria have been received.
Mild adverse reactions have reportedly resolved without treatment. Severe reactions should be treated
symptomatically.
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)

7. TARGET SPECIES

Horses

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

The following procedure is recommended: Use two sterile needles, one to fill the syringe from the bottle and one to inject the patient. Once the required dose has been withdrawn from the vial, the syringe should be removed from the needle. A separate sterile needle should be inserted into the injection site and the syringe connected to it. The needles should be discarded.

1. DOMOSEDAN® alone for sedation:

For parenteral use by IM or slow IV injection. Onset of effect is more rapid following intravenous administration.

Dosage table

Anticipated level of sedation	Light	Moderate	Profound
Dosage (im or iv) µg/kg	10 - 20	20 - 40	40 - 80
Dose (im or iv) ml/100 kg	0.1 - 0.2	0.2 - 0.4	0.4 - 0.8
Commencement of effect (mins)* IV IM	 3 5	 2 5	 1 5
Duration of action (hrs)	0.5 - 1	0.5 - 1	0.5 - 2

*Note these times are approximate and will vary in individual animals.

2. DOMOSEDAN® with butorphanol for sedation

Dosage: 0.10 ml DOMOSEDAN®/100 kg (10 µg/kg detomidine hydrochloride) intravenously, followed within 5 minutes by a dose rate in the region of 25 µg butorphanol/kg (e.g. 0.25ml/100kg of a 10mg/ml solution), intravenously. Clinical experience has shown that 5mg (0.5ml) DOMOSEDAN® and 10mg (e.g. 1ml of a 10 mg/ml solution) butorphanol affords effective, safe sedation in horses above 200 kg bodyweight.

3. DOMOSEDAN® and ketamine (short duration anaesthesia)

Ketamine must not be used as the sole anaesthetic agent in horses. It is always necessary to administer
DOMOSEDAN® prior to ketamine and to allow sufficient time (5 minutes) for sedation to develop. The two agents must therefore never be administered simultaneously in the same syringe. To obtain satisfactory surgical anaesthesia, it is important that the following procedure is used:
Administer DOMOSEDAN® at a dose rate of 20 µg/kg by intravenous injection. Allow 5 minutes for the horse to become deeply sedated then administer ketamine at a dose rate of 2.2 mg/kg as an intravenous bolus. Onset of anaesthesia is gradual, the horse taking approximately 1 minute to become recumbent. In large fit horses recumbency may take up to 3 minutes.

Anaesthesia will continue to deepen for a further 1 - 2 minutes and during this time the horse should be left quietly. Horses regain sternal recumbency approximately 20 minutes post ketamine administration.
The duration of surgical anaesthesia is approximately 10 - 15 minutes and if for any reason it is necessary to prolong anaesthesia, thiopentone sodium can be administered intravenously in boluses of 1 mg/kg as required. Total doses of 5 mg/kg (five 1 mg/kg increments) have been given. Total doses greater than this may reduce the quality of recovery.
Thiopentone can also be administered (as per the above regime) if sufficient depth of anaesthesia is not achieved.The horse should be allowed to stand in its own time. The horse may be ataxic if it stands prematurely and therefore it should be encouraged to remain recumbent.
To facilitate handling and the administration of the induction agents, some horses have received acepromazine by intramuscular injection at a dose rate of 0.03 mg/kg at least 45 minutes before induction of anaesthesia.

9. ADVICE ON CORRECT ADMINISTRATION

The concurrent use of potentiated sulphonamides may cause potentially fatal dysrhythmias. Potentiated sulphonamides should not be administered during sedation with DOMOSEDAN®.
Intravenous administration should be slow.
DOMOSEDAN® must not be mixed with other products.
It is recommended that feed should be withheld for at least 12 hours prior to anaesthesia.
The horse should not be given water or feed before the drug effect has passed.
Routine safety measures should be employed to protect practitioners and handlers.

10. WITHDRAWAL PERIOD(S)

Withdrawal period: meat & offal – 1 day.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not refrigerate or freeze

Shelf life after first opening the container: 3 months

Keep vials in the outer carton

This veterinary medicinal product does not require any special storage conditions.

When the container is broached 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 worked out. This discard date should be written in the space provided on the carton.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Do not administer to horses in the last month of pregnancy.

Special precautions for use in animals:
Do not use in seriously ill animals with heart failure or impaired liver or kidney function.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

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:
Detomidine 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 haemodynamicsymptoms should be treated symptomatically.

Pregnancy and lactation:
Not to be used in mares in the last month of pregnancy.
No studies have been conducted in mares; however trace amounts of detomidine have been detected in the milk of cows treated with the product.
The safety of the product has not been investigated in breeding horses; use only according to benefit/risk assessment during the other months of pregnancy.

Interaction with other medicinal products and other forms of interaction:
Where appropriate DOMOSEDAN® may be used in conjunction with local anaesthetic agents.
Induction of anaesthesia with DOMOSEDAN® and ketamine has been used prior to maintenance with halothane. Because of the nature of the induction agents, the effects of halothane may be delayed and special care must be taken to avoid over-dosage.

Note: When DOMOSEDAN® is used as a premedication prior to general anaesthesia, it may delay onset of induction.

Overdose (symptoms, emergency procedures, antidotes):
Overdose may cause cardiac arrhythmia, hypotension, delayed recovery, and deep depression of the central nervous system and the respiratory system. If recovery is delayed, it should be ensured that the animal can recover in a quiet and warm place. An oxygen supplement may be indicated in circulatory and respiratory depression.

In cases of overdose, or should the effects become life-threatening, an alpha-2 antagonist (atipamezole) is recommended (5-10 times the dose of detomidine in µg/kg).

AV blocks may be prevented by IV administration of atropine at 0.005 - 0.02 mg/kg. Atropine raises the heart rate but may cause arrhythmias and should be used with caution.

Incompatibilities:
Not to be mixed with other products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2020.

15. OTHER INFORMATION

PHARMACEUTICAL PRECAUTIONS
When the container is broached 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 carton.

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

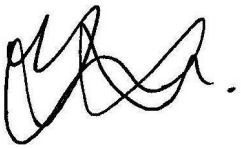
Marketing authorisation number:
Vm 06043/4002

LEGAL CATEGORY
POM-V

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

PACKAGE QUANTITIES
Multidose containers of 20 ml and 5 ml.

Distributed by:
VETOQUINOL UK LIMITED
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northants
NN12 7LS
(+logo)



Approved: 26 June 2020