Sedastart® Solution for Injection for Cats and Dogs
Active substance: Medetomidine hydrochloride

Presentation: Sedastart is a clear, colourless, sterile aqueous solution for injection containing:
Active substance: Medetomidine hydrochloride 1.0mg/ml (equivalent to 0.85mg/ml medetomidine)
Excipients: Methylparahydroxybenzoate \((E218)\) 1.0mg/ml Propylparahydroxybenzoate 0.2mg/ml

Indications
In Dogs and Cats: Sedation to facilitate handling.
In Cats: In combination with ketamine for general anaesthesia for minor surgical procedures of short duration.

Contraindications
Do not use in animals with:
- severe cardiovascular disease or respiratory diseases or impaired liver or kidney function
- mechanical disturbances of the gastrointestinal tract (tumours, perforations, obstructions)
- pregnancy
- diabetes mellitus
- state of shock, emaciation or severe debilitation
Do not use concomitantly with sympathomimetic amines.
Do not use in cats of known hypersensitivity to the active substance or to any other excipients.
Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.

Adverse reactions
Adrenergic crisis with atrial fibrillation (1st and 2nd degree) and occasionally extrasystoles. Vasodilatation of coronary artery. Decreased cardiac output. Blood pressure will increase initially after administration and then return to normal, or slightly below normal. In rare cases, pulmonary oedema has been reported, especially in cats. Death from circulatory failure with severe congestion of the lungs, liver or kidney has been reported. Respiratory depression may occur, cyanosis. In circulatory and respiratory depression manual ventilation and an oxygen supplement may be indicated. Atropine may increase the cardiac rate. Some dogs and most cats will vomit within 5-10 minutes of injection. Cats may also vomit on recovery. Sensitivity to loud noises is often observed in some individuals. Increased diuresis. Hypothermia. Pain at injection site and muscle tremor may be seen. In individual cases reversible hyperglycaemia due to depression of insulin secretion.

Dosage, route and method of administration
For sedation the veterinary medicinal product should be administered at the rate of 0.05-0.1 mg/kg body weight intravenously or intramuscularly.

Table:

Table: Dosage for Cats and Dogs

<table>
<thead>
<tr>
<th>Species</th>
<th>Body Weight (kg)</th>
<th>Dosage (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dogs</td>
<td>&gt;10</td>
<td>0.1</td>
</tr>
<tr>
<td>Dogs</td>
<td>&lt;10</td>
<td>0.2</td>
</tr>
<tr>
<td>Cats</td>
<td></td>
<td>0.1</td>
</tr>
</tbody>
</table>

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

Target species
Dogs and cats.

Dosage, route and method of administration
The veterinary medicinal product is intended for:
Dogs: Intravenous or intramuscular use.
Cats: Intramuscular use.

Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

Dogs: For sedation the veterinary medicinal product should be administered at the rate of 1750µg per kg body weight. Maximal effect is obtained within 15-20 minutes. Clinical effect is dose-dependent, lasting from 3 to 180 minutes.
The dose should furthermore be adjusted to the type of drugs used and the dosage(s) of the other drug(s). The exact dose depends on the combination products should be observed. See also Special precautions section.

Advice on correct administration

Withdrawal period

Not applicable

Special storage precautions

Keep out of the sight and reach of children. Do not freeze. Do not use this veterinary medicinal product after the expiry date which is stated on the label and on the carton after EXP. Shelf-life after first opening the container: 28 Days. When the container is1 broached (opened) for the first time, using the invio shelf life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

Special warnings

Medetomidine may not provide analgesia and under these circumstances, manual ventilation and oxygen administration may be being administered. This discard date should be written in the space provided. This discard date should be written in the space provided.

Medetomidine may not provide analgesia and under these circumstances, manual ventilation and oxygen may be administered. Special precautions to be taken by the person administering the veterinary medicinal product to animals. In the case of accidental or intakes of atipamezole, seek medical advice immediately and show the package insert to the physician but DO NOT DRIVE as sedation and changes in blood pressure may increase. Avoid skin, eye or mucosal contact. Wash the exposed skin immediately after exposure. Avoid skin, eye or mucosal contact. Wash the exposed skin immediately after exposure. Avoid skin, eye or mucosal contact. Wash the exposed skin immediately after exposure.

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For premedication, the veterinary medicinal product should be administered at a dosage of 10–40µg medetomidine hydrochloride per kg body weight, corresponding to ~0.1–0.4ml product per 10kg body weight. The exact dose depends on the combination of drugs used and the dosage(s) of the other drug(s). The dose should furthermore be adjusted to the type of surgery, length of procedure and patient temperament and weight. Premedication with medetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. All anaesthetic agents used for induction or maintenance of anaesthesia should be observed. See also Special precautions section.

Cats: For moderate-deep sedation and restraint of cats the veterinary medicinal product should be administered at a dosage of 0.5–1.5µg medetomidine hydrochloride/kg bw (corresp. to 0.03–0.06ml product/kg bw) intramuscularly in the dog in the same volume as 2.5–3.75mg ketamine/kg bw (corresp. to 0.56–0.80mg product/kg bw).

For anaesthesia the veterinary medicinal product should be administered at a dosage of 80µg medetomidine hydrochloride/kg bw (corresp. to 0.05–0.15ml product/kg bw). For premedication, the veterinary medicinal product should be administered at a dosage of 50–150µg medetomidine hydrochloride/kg bw (corresp. to 1.03–3.08mg product/kg bw).

Advice on correct administration

Withdrawal period

Not applicable

Special storage precautions

Keep out of the sight and reach of children. Do not freeze. Do not use this veterinary medicinal product after the expiry date which is stated on the label and on the carton after EXP. Store after first opening the container: 28 days. When the container is broached (opened) for the first time, using the invoiced shelf life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

Special warnings

Medetomidine has marked anaesthetic sparing effect. Appropriate dose adjustment should be made. As ketamine alone can elicit cramps, alpha-2-agonists should not be administered before 30–40 minutes after ketamine. Medetomidine may cause respiratory depression and under these circumstances, manual ventilation and oxygen may be administered. Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental and intake or allergic reaction, 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. Wash exposed skin immediately after exposure with large amounts of water. Remove contaminated clothes that are in direct contact with skin.

In the case of accidental contact of the product with eyes, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician. If pregnant women handle the product, special caution should be observed not to reject vomiting or the decrease of blood pressure may occur after accidental systemic exposure. In the case of overdose the main signs are cardio-respiratory effects of an overdose it is recommended to administer an alpha-2 antagonist e.g. atipamezole or yohimbine, provided that reversal of sedation is not dangerous to the patient (atipamezole does not reverse the effects of ketamine which may cause seizures in dogs and elicit cramps in cats when used alone). Use atipamezole hydrochloride 0.3mg/ml intramuscularly in the dog in the same volume as medetomidine hydrochloride 1mg/ml, in the cat use half the volume. The required dose of atipamezole hydrochloride corresponds in dogs to the 5–10-fold of the medetomidine hydrochloride dose in mg administered before and in cats to the 10–20-fold dose. As ketamine dose is highly dependent the dose can be administered before 30–40 minutes after ketamine. In the case of accidental contact with eyes or skin, wash immediately with large amounts of water. Avoid skin, eye or mucosal contact. Use atipamezole hydrochloride 0.3mg/ml intramuscularly in the dog in the same volume as medetomidine hydrochloride 1mg/ml, in the cat use half the volume. The required dose of atipamezole hydrochloride corresponds in dogs to the 5–10-fold of the medetomidine hydrochloride dose in mg administered before and in cats to the 10–20-fold dose. As ketamine dose is highly dependent the dose can be administered before 30–40 minutes after ketamine. In the case of accidental contact with eyes or skin, wash immediately with large amounts of water.

Advice to doctors

Medetomidine is an alpha-2-adrenerceptor agonist. Symptoms after absorption may involve cardiovascular and haemodynamic symptoms should be treated symptomatically.

Use during pregnancy or lactation

If it is imperative to reverse sedation without anaesthesia, atipamezole or yohimbine should be used. The safety of the product has not been established in the case of pregnancy or lactation.

Overdose (symptoms, emergency procedure)

In the case of overdose the main signs are cardio-respiratory effects of an overdose it is recommended to administer an alpha-2 antagonist e.g. atipamezole or yohimbine.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
sedastart® 1mg/ml
Solution for Injection for Cats and Dogs
Active substance: Medetomidine hydrochloride

Presentation: Sedastart is a clear, colourless, sterile aqueous solution for injection containing:

Active substance: Medetomidine hydrochloride 1.0mg/ml (equivalent to 0.85mg/ml medetomidine)
Excipients:
- Propyl parahydroxybenzoate {E218} 1.0mg/ml
- Propyl parahydroxybenzoate 0.2mg/ml

Indications
In Dogs and Cats: Sedation to facilitate handling
In Cats: In combination with ketamine for general anaesthesia for minor surgical procedures of short duration.

Contraindications
Do not use in animals with:
- severe cardiovascular disease or respiratory diseases or impaired liver or kidney function
- mechanical disturbances of the gastrointestinal tract (torto ventriculi, incarcerations, oesophageal obstructions)
- pregnancy
- diabetes mellitus
- state of shock, emaciation or serious debilitation
Do not use concurrently with sympathomimetic amines.
Do not use in cases of known hypersensitivity to the active substance or to any other excipients.
Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.

Adverse reactions
Cardiopulmonary arrest with atrioventricular block (1st and 2nd degree) and occasionally extrasystolia. Vasodilatation of coronary artery. Decreased cardiac output. Blood pressure will increase initially after administration and return to normal, or slightly below normal. In rare cases, pulmonary oedema has been reported, especially in cats. Death from circulatory failure with severe congestion of the lungs, liver or kidneys has been reported. Respiratory depression may occur, cyanosis. In circulatory and respiratory depression manual ventilation and an oxygen supplement may be indicated. Atropine may increase the cardiac rate. Some dogs and most cats will vomit within 5-10 minutes of injection. Cats may also vomit on recovery. Sensitivity to loud noises is observed in some individuals. Increased diaurexia, hypothermia. Pain at injection site and muscle tremor may be seen. In individual cases reversible hyperthermia due to depression of insulin secretion.

Dogs: with a body weight of less than 10kg may show the undesirable effects mentioned above more often.

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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

Target species
Dogs and cats.

Dosage, route and method of administration
The veterinary medicinal product is intended for:

Dogs: Intramuscular or intravenous use.

Cats: Intramuscular use.

Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

Dogs: For sedation the veterinary medicinal product should be administered at the rate of 7.5µg/kg medetomidine hydrochloride IV or 10µg/kg medetomidine hydrochloride IM per square metre of body surface. Use the table overleaf to determine the correct dosage on the basis of body weight.
Maximal effect is obtained within 15-20 minutes. Clinical effect is dose-dependent, lasting from 30-180 minutes.

Contraindications
Do not use in animals with:
- diabetes mellitus
- pregnancy
- mechanical disturbances of the gastrointestinal tract (torto ventriculi, incarcerations, oesophageal obstructions)

Product information
Distributed by:
4949 SJ Raamsdonksveer, The Netherlands
Produlab Pharma B.V., Forellenweg 16, The Netherlands
Manufacturer responsible for batch release:
The Netherlands
Marketing authorisation holder:
Not all pack sizes may be marketed.
Other information
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