

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexmedocord 0.5 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

One ml contains 0.5 mg dexmedetomidine hydrochloride equivalent to 0.42 mg dexmedetomidine.

Excipients:

| | |
|------------------------------------|---------------|
| Methyl parahydroxybenzoate (E 218) | 1.6 mg/ml |
| Propyl parahydroxybenzoate (E 216) | 0.2 mg/ml |
| Sodium chloride | 9.0 mg/ml |
| Water for injection | q.s to 1.0 ml |
| Nitrogen gas | q.s to sparge |

3. CLINICAL INFORMATION

3.1 Target species

Dogs and Cats

3.2 Indications for use for each target species

Non-invasive, mildly to moderately painful, procedures and examinations which require restraint, sedation and analgesia in dogs and cats.

Deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures.

Premedication in dogs and cats before induction and maintenance of general anaesthesia.

3.3 Contraindications

Do not use in animals with cardiovascular disorders.

Do not use in animals with severe systemic disease or in animals that are moribund.

Do not use in case of known hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

The administration of dexmedetomidine to puppies younger than 16 weeks and kittens younger than 12 weeks has not been studied.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Treated animals should be kept warm and at a constant temperature, both during the procedure and recovery.

It is recommended that animals are fasted for 12 hours prior to administration of the veterinary medicinal product. Water may be given.

After treatment, the animal should not be given water or food before it is able to swallow.

In cats, corneal opacities may occur during sedation.
In both target species the eyes should be protected by a suitable lubricant.

To be used with precaution in elderly animals.

The safety of dexmedetomidine has not been established in males intended for breeding.

Nervous, aggressive or excited animals should be given the possibility to calm down before initiation of treatment.

Frequent and regular monitoring of respiratory and cardiac function should be performed. Pulse oximetry may be useful but is not essential for adequate monitoring. Equipment for manual ventilation should be available in case of respiratory depression or apnoea when dexmedetomidine and ketamine are used sequentially to induce anaesthesia in cats. It is also advisable to have oxygen readily available, should hypoxaemia be detected or suspected.

Sick and debilitated dogs and cats should only be premedicated with dexmedetomidine before induction and maintenance of general anaesthesia based on a risk-benefit assessment.

Use of dexmedetomidine as a premedicant in dogs and cats significantly reduces the amount of induction medicinal product required for induction of anaesthesia. Attention should be given during the administration of intravenous induction medicinal products to effect.
Volatile anaesthetic requirements for maintenance anaesthesia are also reduced.

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

This product can cause sedation and changes in blood pressure after oral, dermal, mucosal, and parenteral exposure. Avoid skin, eye, or mucosal contact; the use of impermeable gloves is advisable.

In case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet or the label to the physician, but DO NOT DRIVE.

In case of skin or mucosal contact, wash the exposed skin immediately after exposure with large amounts of water and remove contaminated clothes that are in direct contact with skin. In case of eye contact, 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 self-inject, as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

People with known hypersensitivity to dexmedetomidine or parabens should administer the product with caution.

To the physician:

Dexmedetomidine is an α_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. The specific α_2 -adrenoceptor antagonist, atipamezole, which is approved for use in animals, has been used in humans only experimentally to antagonize dexmedetomidine-induced effects.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Not applicable.

3.6 Adverse events

Dogs:

| | |
|---|--|
| <u>Very common (> 1 animal / 10 animals treated):</u> | <u>Bradycardia¹</u> <u>Cyanotic mucous membranes², Pale mucous membranes²</u> |
| <u>Rare (1 to 10 animals / 10,000 animals treated):</u> | <u>Pulmonary oedema</u> |
| <u>Undetermined frequency (cannot be estimated from the available data)</u> | <u>High blood pressure³, Low blood pressure³</u> <u>Bradypnoea</u> <u>Hypothermia¹</u> <u>Vomiting⁴</u> <u>Muscle tremor</u> <u>Corneal opacity</u> |
| When dexmedetomidine and butorphanol are used concomitantly: | |
| <u>Common (1 to 10 animals / 100 animals treated):</u> | <u>Arrhythmia⁵</u> |
| <u>Undetermined frequency (cannot be estimated from the available data)</u> | <u>Bradypnoea, Tachypnoea, Irregular breathing⁶,</u> <u>Hypoxia</u> <u>Muscle tremor, Twitching, Paddling, Sedation</u> <u>prolonged</u> <u>Excitation</u> <u>Hypersalivation, Retching, Vomiting</u> <u>Urination</u> <u>Erythema</u> |
| When dexmedetomidine is used as a pre-medicant: | |
| <u>Rare (1 to 10 animals / 10,000 animals treated):</u> | <u>Arrhythmia⁷</u> |
| <u>Undetermined frequency (cannot be estimated from the available data)</u> | <u>Arrhythmia⁸</u> <u>Bradypnoea, Tachypnoea</u> <u>Vomiting</u> |

¹By virtue of the α 2-adrenergic activity of dexmedetomidine.

²Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation.

³Blood pressure will increase initially and then return to normal or below normal.

⁴May occur 5–10 minutes after injection. Some dogs and cats may also vomit at the time of recovery.

⁵Brady- and tachyarrhythmias. These may include profound sinus bradycardia, 1st and 2nd degree AV block, sinus arrest or pause, as well as atrial, supraventricular and ventricular premature complexes.

⁶20-30 sec apnoea followed by several rapid breaths.

⁷Supraventricular and ventricular premature complexes, sinus pause and 3rd degree AV block.

⁸Brady- and tachyarrhythmias have been reported and include profound sinus bradycardia, 1st and 2nd degree AV block and sinus arrest.

Cats:

| | |
|---|--|
| <u>Very common</u> (<u>> 1 animal / 10 animals treated</u>): | <u>Bradycardia</u> ¹ <u>Vomiting</u> ² <u>Cyanotic mucous membranes</u> ³ , <u>Pale mucous membranes</u> ³ |
| <u>Rare</u> (<u>1 to 10 animals / 10,000 animals treated</u>): | <u>Pulmonary oedema</u> |
| <u>Undetermined frequency</u> (<u>cannot be estimated from the available data</u>) | <u>High blood pressure</u> ⁴ , <u>Low blood pressure</u> ⁴ <u>Bradypnoea</u> <u>Hypothermia</u> ¹ <u>Muscle tremor</u> <u>Corneal opacity</u> |
| When dexmedetomidine and ketamine are used sequentially (with a 10 min | |
| <u>Very common</u> (<u>> 1 animal / 10 animals treated</u>): | <u>Heart block</u> |
| <u>Common</u> (<u>1 to 10 animals / 100 animals treated</u>): | <u>Hypoxia/Decreased pulse oxygenation</u> ⁵ , <u>Hypothermia</u> |
| <u>Uncommon</u> (<u>1 to 10 animals / 1,000 animals treated</u>) | <u>Apnoea</u> |
| <u>Undetermined frequency</u> (<u>cannot be estimated from the available data</u>) | <u>Bradypnoea, Irregular breathing</u> <u>Hypoventilation</u> <u>Vomiting</u> <u>Extrasystole</u> <u>Nervousness</u> |
| When dexmedetomidine is used as a pre-medicant: | |
| <u>Very common</u> (<u>> 1 animal / 10 animals treated</u>): | <u>Arrhythmia</u> ^{6,7} |
| <u>Common</u> (<u>1 to 10 animals / 100 animals treated</u>) | <u>Sinus bradycardia</u> ⁶ , <u>Sinus arrhythmia</u> ⁶ , <u>Supraventricular and nodal arrhythmia</u> , <u>Retching</u> |
| <u>Uncommon</u> (<u>1 to 10 animals / 1,000 animals treated</u>) | <u>Heart block 1st degree</u> ⁶ |
| <u>Undetermined frequency</u> (<u>cannot be estimated from the available data</u>) | <u>Vomiting</u> <u>Pale mucous membranes</u> <u>Hypothermia</u> |

¹By virtue of the α 2-adrenergic activity of dexmedetomidine.

²May occur 5–10 minutes after injection. Some dogs and cats may also vomit at the time of recovery.

³Due to peripheral vasoconstriction and venous desaturation in the presence of normal arterial oxygenation.

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

⁵Especially within the 15 first minutes of anaesthesia.

⁶After intramuscular dosing at 40 micrograms/kg (followed by ketamine or propofol).

⁷Supraventricular premature complexes, atrial bigeminy, sinus pauses, 2nd degree AV block, escape beats/rhythms.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder 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 and lactation. The use is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

The use of other central nervous system depressants is expected to potentiate the effects of dexmedetomidine and therefore an appropriate dose adjustment should be made. Anticholinergics should be used with caution with dexmedetomidine.

Administration of atipamezole after dexmedetomidine rapidly reverses the effects and thus shortens the recovery period. Within 15 minutes dogs and cats are normally awake and standing.

Cats: After administration of 40 micrograms dexmedetomidine/kg bw intramuscularly concurrently with 5 mg ketamine/kg bw to cats, the maximum concentration of dexmedetomidine increased twofold but there was no effect on T max. The mean half-life of elimination of dexmedetomidine increased to 1.6 h and the total exposure (AUC) increased by 50%.

A dose of 10 mg ketamine/ kg used concurrently with 40 micrograms dexmedetomidine/kg may cause tachycardia.

Atipamezole does not reverse the effect of ketamine.

3.9 Administration routes and dosage

The product is intended for:

- Dogs: intravenous or intramuscular use
- Cats: intramuscular use

The product is not intended for repeat injections.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The vial should not be broached more than 24 times.

Dose: the following doses are recommended:

DOGS:

Dexmedetomidine doses are based on body surface area:

Intravenously: up to 375 micrograms/square metre body surface area

Intramuscularly: up to 500 micrograms/square metre body surface area

When administering in conjunction with butorphanol (0.1 mg/kg) for deep sedation and analgesia, the intramuscular dose of dexmedetomidine is 300 micrograms/square metre body surface area. The premedication dose of dexmedetomidine is 125–375 micrograms/square metre body surface area, administered 20 minutes prior to induction for procedures requiring anaesthesia. The dose should be adjusted to the type of surgery, length of procedure and patient temperament.

Concomitant use of dexmedetomidine and butorphanol produces sedative and analgesic effects beginning no later than 15 minutes. The peak sedative and analgesic effects are reached within 30 minutes after administration. Sedation lasts for at least 120 minutes post administration and analgesia lasts for at least 90 minutes. Spontaneous recovery occurs within 3 hours.

Premedication with dexmedetomidine will significantly reduce the dose of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. In a clinical study, the requirement for propofol and thiopental was reduced by 30% and 60% respectively. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect. In a clinical study, dexmedetomidine contributed to postoperative analgesia for 0.5–4 hours. However this duration is dependent on a number of variables and further analgesia should be administered in accordance with clinical judgement.

The corresponding doses based on body weight are presented in the following tables. Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

| Dog weight (kg) | Dexmedetomidine 125 mcg/m² | | Dexmedetomidine 375 mcg/m² | | Dexmedetomidine 500 mcg/m² | |
|----------------------------|--|-------------|--|-------------|--|-------------|
| | (mcg/kg) | (ml) | (mcg/kg) | (ml) | (mcg/kg) | (ml) |
| 2-3 | 9.4 | 0.04 | 28.1 | 0.12 | 40 | 0.15 |
| 3-4 | 8.3 | 0.05 | 25 | 0.17 | 35 | 0.2 |
| 4-5 | 7.7 | 0.07 | 23 | 0.2 | 30 | 0.3 |
| 5-10 | 6.5 | 0.1 | 19.6 | 0.29 | 25 | 0.4 |
| 10-13 | 5.6 | 0.13 | 16.8 | 0.38 | 23 | 0.5 |
| 13-15 | 5.2 | 0.15 | 15.7 | 0.44 | 21 | 0.6 |
| 15-20 | 4.9 | 0.17 | 14.6 | 0.51 | 20 | 0.7 |
| 20-25 | 4.5 | 0.2 | 13.4 | 0.6 | 18 | 0.8 |
| 25-30 | 4.2 | 0.23 | 12.6 | 0.69 | 17 | 0.9 |
| 30-33 | 4 | 0.25 | 12 | 0.75 | 16 | 1.0 |
| 33-37 | 3.9 | 0.27 | 11.6 | 0.81 | 15 | 1.1 |
| 37-45 | 3.7 | 0.3 | 11 | 0.9 | 14.5 | 1.2 |
| 45-50 | 3.5 | 0.33 | 10.5 | 0.99 | 14 | 1.3 |
| 50-55 | 3.4 | 0.35 | 10.1 | 1.06 | 13.5 | 1.4 |
| 55-60 | 3.3 | 0.38 | 9.8 | 1.13 | 13 | 1.5 |
| 60-65 | 3.2 | 0.4 | 9.5 | 1.19 | 12.8 | 1.6 |
| 65-70 | 3.1 | 0.42 | 9.3 | 1.26 | 12.5 | 1.7 |
| 70-80 | 3 | 0.45 | 9 | 1.35 | 12.3 | 1.8 |
| >80 | 2.9 | 0.47 | 8.7 | 1.42 | 12 | 1.9 |

| For deep sedation and analgesia with butorphanol | | |
|---|--|-------------|
| Dog weight (kg) | Dexmedetomidine 300 mcg/m² intramuscularly | |
| | (mcg/kg) | (ml) |
| 2-3 | 24 | 0.12 |
| 3-4 | 23 | 0.16 |
| 4-5 | 22.2 | 0.2 |
| 5-10 | 16.7 | 0.25 |
| 10-13 | 13 | 0.3 |
| 13-15 | 12.5 | 0.35 |
| 15-20 | 11.4 | 0.4 |
| 20-25 | 11.1 | 0.5 |
| 25-30 | 10 | 0.55 |
| 30-33 | 9.5 | 0.6 |
| 33-37 | 9.3 | 0.65 |
| 37-45 | 8.5 | 0.7 |
| 45-50 | 8.4 | 0.8 |
| 50-55 | 8.1 | 0.85 |
| 55-60 | 7.8 | 0.9 |
| 60-65 | 7.6 | 0.95 |
| 65-70 | 7.4 | 1 |
| 70-80 | 7.3 | 1.1 |
| >80 | 7 | 1.2 |

CATS:

The dose for cats is 40 micrograms dexmedetomidine hydrochloride/kg bw equal to a dose volume of 0.08 ml of the veterinary medicinal product/kg bw when used for non-invasive, mildly to moderately painful procedures requiring restraint, sedation and analgesia.

When the product is used for premedication in cats, the same dose is used. Premedication with dexmedetomidine will significantly reduce the dose of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. In a clinical study, the requirement for propofol was reduced by 50%. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect.

Anaesthesia can be induced 10 minutes after premedication by intramuscular administration of a target dose of 5 mg ketamine/ kg bw or by intravenous administration of propofol to effect. Dosing for cats is presented in the following table.

| Cat weight (kg) | Dexmedetomidine 40 mcg/kg intramuscularly | |
|--------------------|---|------|
| | (mcg/kg) | (ml) |
| 1-2 | 40 | 0.1 |
| 2-3 | 40 | 0.2 |
| 3-4 | 40 | 0.3 |
| 4-6 | 40 | 0.4 |
| 6-7 | 40 | 0.5 |
| 7-8 | 40 | 0.6 |
| 8-10 | 40 | 0.7 |

The expected sedative and analgesic effects are reached within 15 minutes after administration and are maintained up to 60 minutes after administration. Sedation may be reversed with atipamezole. Atipamezole should not be administered prior to 30 minutes following ketamine administration.

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

Dogs:

In cases of overdose, or if the effects of dexmedetomidine become potentially life-threatening, the appropriate dose of atipamezole is 10 times the initial dose of dexmedetomidine (micrograms/ kg bw or micrograms/ square meter body surface area). The dose volume of atipamezole at the concentration of 5 mg/ml equals the dose volume of the veterinary medicinal product that was given to the dog, regardless of route of administration of the product.

Cats:

In cases of overdose, or if the effects of dexmedetomidine become potentially life-threatening, the appropriate antagonist is atipamezole, administered by intramuscular injection, at the following dose: 5 times the initial dose dexmedetomidine in micrograms/kg bw.

The dose volume of atipamezole at the concentration of 5 mg/ml equals one-half the volume of the veterinary medicinal product that was given to the cat.

After concurrent exposure to a threefold overdose of dexmedetomidine and 15 mg ketamine/ kg, atipamezole can be administered at the recommended dose level for reversal of effects induced by dexmedetomidine.

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:

ATCvet code: QN05CM18

4.2 Pharmacodynamics

The veterinary medicinal product contains dexmedetomidine as the active substance, which produces sedation and analgesia in dogs and cats. The duration and depth of the sedation and analgesia are dose-dependent. At maximal effect, the animal is relaxed, recumbent and does not respond to external stimulus.

Dexmedetomidine is a potent and selective α_2 -adrenoceptor agonist that inhibits the release of noradrenaline from noradrenergic neurons. Sympathetic neurotransmission is prevented and the level of consciousness decreases. Reduced heart rate and temporary AV-block can be seen after administration of dexmedetomidine. Blood pressure decreases to normal or below normal levels after an initial increase. Respiration rate can occasionally decrease. Dexmedetomidine also induces a number of other α_2 -adrenoceptor mediated effects, which include piloerection, depression of motor and secretory functions of the gastrointestinal tract, diuresis and hyperglycaemia.

A slight decrease in temperature may be observed.

4.3 Pharmacokinetics

As a lipophilic compound, dexmedetomidine is well absorbed after intramuscular administration. Dexmedetomidine is also rapidly distributed in the body and penetrates the blood-brain barrier readily.

According to studies in rats, the maximum concentration in the central nervous system is several times that of the corresponding concentration in plasma. In the circulation, dexmedetomidine is largely bound to plasma proteins (>90%).

Dogs: After an intramuscular dose of 50 micrograms/kg a maximum concentration in plasma of about 12 ng/ml is reached after 0.6 hours. The bioavailability of dexmedetomidine is 60% and the apparent volume of distribution (Vd) is 0.9 l/kg. The elimination half-life ($t_{1/2}$) is 40-50 minutes.

Major biotransformations in the dog include hydroxylation, glucuronic acid conjugation and N-methylation in the liver. All known metabolites lack pharmacological activity. Metabolites are excreted mainly in the urine and to a lesser extent in the faeces. Dexmedetomidine has a high clearance and its elimination depends on the hepatic blood flow. A prolonged elimination half-life is therefore expected with overdoses or when dexmedetomidine is coadministered with other substances, which affect hepatic circulation.

Cats: The maximum plasma concentration is reached about 0.24 h after intramuscular administration. After a 40 micrograms/kg bw intramuscular dose the C_{max} is 17 ng/ml. The apparent volume of distribution (Vd) is 2.2 l/kg and the elimination half-life ($t_{1/2}$) is one hour.

Biotransformations in the cat occur by hydroxylation in the liver. Metabolites are excreted mainly in the urine (51% of the dose), and to a lesser extent in the faeces. As in dogs dexmedetomidine has a high clearance in cats and its elimination depends on the hepatic blood flow. A prolonged elimination half-life is therefore expected with overdoses or when dexmedetomidine is coadministered with other substances, which affect hepatic circulation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging: After withdrawal of the first dose, the product may be stored for 3 months at 20°C - 25°C.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I clear glass vial with a fluoropolymer coated rubber stopper and an aluminium overseal.

Pack sizes:

Cardboard box containing one 10 ml vial

Cardboard box containing ten 10 ml vials

Not all pack sizes may be marketed.

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.

The veterinary medicinal product should not enter water courses as dexmedetomidine may be dangerous for fish and other aquatic organisms.

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

Accord Healthcare B.V

7. MARKETING AUTHORISATION NUMBER

Vm 42153/5000

8. DATE OF FIRST AUTHORISATION

15 January 2025

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

January 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: 21 May 2025