

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

0.5 mg dexmedetomidine hydrochloride equivalent to 0.42 mg dexmedetomidine.

3. PACKAGE SIZE

10 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: intravenous or intramuscular use

Cats: intramuscular use

7. WITHDRAWAL PERIODS

Not applicable

8. EXPIRY DATE

EXP:

Shelf life after first opening: 3 months at 20°C – 25°C

9. SPECIAL STORAGE PRECAUTIONS

This medicinal product does not require any special storage conditions.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Accord Healthcare B.V
Winthontlaan 200
P. O. Box 95
Utrecht
3526 KV
The Netherlands

14. MARKETING AUTHORISATION NUMBER

Vm 42153/5000

15. BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

0.5 mg dexmedetomidine hydrochloride equivalent to 0.42 mg dexmedetomidine.

4. ROUTES OF ADMINISTRATION

Dogs: IV, IM

Cats: IM

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

EXP:

Shelf life after first opening: 3 months at 20°C – 25°C

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Accord Healthcare B.V

9. BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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. Target species

Dogs and cats

4. Indications for use

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.

5. 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.

6. Special warnings

Special warnings:

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

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. 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 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.

Pregnancy and lactation:

The safety of dexmedetomidine has not been established during pregnancy and lactation in the target species. Therefore, the use of the product during pregnancy and lactation is not recommended.

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.

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 two fold 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.

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.

Atipamezole does not reverse the effect of ketamine.

For information on adverse reactions, see section: Adverse reactions.

Overdose:

In cases of overdosing the following recommendations should be followed:

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 5mg/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.

Major incompatibilities:

None known.

7. Adverse events

Dogs:

Very common (> 1 animal / 10 animals treated):	Bradycardia ¹ Cyanotic mucous membranes ² , Pale mucous membranes ²
Rare (1 to 10 animals /10,000 animals treated):	Pulmonary oedema
Undetermined frequency (cannot be estimated from the available data)	High blood pressure ³ , Low blood pressure ³ Bradypnoea Hypothermia ¹ Vomiting ⁴ Muscle tremor Corneal opacity
When dexmedetomidine and butorphanol are used concomitantly:	
Common (1 to 10 animals / 100 animals treated):	Arrhythmia ⁵
Undetermined frequency (cannot be estimated from the available data)	Bradypnoea, Tachypnoea, Irregular breathing ⁶ , Hypoxia Muscle tremor, Twitching, Paddling, Sedation prolonged Excitation Hypersalivation, Retching, Vomiting Urination Erythema
When dexmedetomidine is used as a pre-medicant:	
Rare (1 to 10 animals / 10,000 animals treated):	Arrhythmia ⁷

Undetermined frequency (cannot be estimated from the available data)	Arrhythmia ⁸ Bradypnoea, Tachypnoea Vomiting
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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:

Very common (> 1 animal / 10 animals treated):	Bradycardia ¹ Vomiting ² Cyanotic mucous membranes ³ , Pale mucous membranes ³
Rare (1 to 10 animals / 10,000 animals treated):	Pulmonary oedema.
Undetermined frequency (cannot be estimated from the available data)	High blood pressure ⁴ , Low blood pressure ⁴ Bradypnoea Hypothermia ¹ Muscle tremor Corneal opacity

When dexmedetomidine and ketamine are used sequentially (with a 10 min

Very common (> 1 animal / 10 animals treated):	Heart block
Common (1 to 10 animals / 100 animals treated):	Hypoxia/Decreased pulse oxygenation ⁵ , Hypothermia
Uncommon (1 to 10 animals / 1,000 animals treated)	Apnoea
Undetermined frequency (cannot be estimated from the available data)	Bradypnoea, Irregular breathing Hypoventilation Vomiting Extrasystole Nervousness

When dexmedetomidine is used as a pre-medicant:

Very common (> 1 animal / 10 animals treated):	Arrhythmia ^{6,7}
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Common (1 to 10 animals / 100 animals treated)	Sinus bradycardia ⁶ , Sinus arrhythmia ⁶ , Supraventricular and nodal arrhythmia Retching
Uncommon (1 to 10 animals / 1,000 animals treated)	Heart block 1st degree ⁶
Undetermined frequency (cannot be estimated from the available data)	Vomiting Pale mucous membranes Hypothermia

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

The product is intended for:

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

The product is not intended for repeat injections.

The vial should not be broached more than 24 times.

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 after administration. 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 dosage 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	Dexmedetomidine 300 mcg/m² intramuscularly	
(kg)	(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	Dexmedetomidine 40 mcg/kg intramuscularly	
(kg)	(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
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9. Advice on correct administration

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.

10. Withdrawal periods

Not applicable

11. Special storage precautions

After withdrawal of the first dose, the product may be stored for 3 months at 20°C-25°C. Keep out of the sight and reach of children. Do not use this medicinal product after the expiry date which is stated on the label and carton after EXP.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42153/5000

Package size: 10 ml, 10 x 10 ml.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Accord Healthcare B.V.

Winthontlaan 200

P. O. Box 95

Utrecht

3526 KV

The Netherlands

Manufacturer responsible for batch release:

Laboratori Fundació DAU

Calle Lletra C De La Zona Franca 12-14, Poligono Industrial De La Zona Franca De Barcelona, Barcelona, 08040, Spain.

17. Other information

POM-V

Gavin Hall

Approved: 21 May 2025