PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dexadreson, 2 mg/ml, solution for injection for cattle, horses, pigs, dogs and cats.

2. Composition

Each ml contains:

Active substance:
Dexamethasone (as sodium phosphate) 2 mg
Excipients:
Benzyl alcohol 15.6 mg

Clear, colorless solution for parenteral injection.
pH 7.0-7.8

3. Target species

Cattle, horses, pigs, dogs and cats.

4. Indications for use

Conditions where the glucocorticoids anti-inflammatory, anti-allergical, immunosuppressive or glucogenetic effects are desired.
This veterinary medicinal product gives a shock effect with short duration.

5. Contraindications

This veterinary medicinal product should not be used during pregnancy's last trimester or to animals with Cushing disease.

6. Special warnings

Special precautions for safe use in the target species:
Use with caution if there is suspicion of ulcus ventriculi, diabetes mellitus, corneal ulcer, fungal and virus infections, renal insufficiency or congestive heart failure.
If administered concurrently with bacterial infections, antibiotics should be administered as well.
Due to dexamethasone's immunosuppressive abilities, concurrent vaccination should be avoided.
Use on young or older individuals, can cause increased risk of side effects. A reduced dose and clinical observation during an eventual treatment is therefore necessary.

Pregnancy:
Administration in early pregnancy may cause fetal abnormalities or delayed fetal growth.
Administration in late pregnancy may cause early parturition or abortion.
Treatment of pregnant animal should be avoided and should only be done according to the responsible veterinarians risk-benefit evaluation.

Interaction with other medicinal products and other forms of interaction:
Dexamethasone should not be given together with other anti-inflammatory drugs.

Overdose:
High doses can cause drowsiness and lethargy in horse. When treating with a high dose, thrombosis complications can occur due to increased clotting propensity

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Pigs, dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Other blood disorder (increase in potassium and calcium excretion, sodium and water retention)[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperglycaemia[2] Muscle atrophy Delayed healing Skin textural change (atrophy) Hypersensitivity

[1] Dexamethasone may therefore potentiate the effect of a certain kind of heart medicines (cardiac glycosides)
[2] Increased glycogenesis, worsening of diabetes mellitus and latent diabetes mellitus can be manifested

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Other blood disorder (increase in potassium and calcium excretion, sodium and water retention)[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperglycaemia[2] Muscle atrophy Delayed healing Skin textural change (atrophy) Hypersensitivity Milk production decrease

[1] Dexamethasone may therefore potentiate the effect of a certain kind of heart medicines (cardiac glycosides)
[2] Increased glycogenesis, worsening of diabetes mellitus and latent diabetes mellitus can be manifested

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Other blood disorder (increase in potassium and calcium excretion, sodium and water retention)[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperglycaemia[2] Muscle atrophy Delayed healing Skin textural change (atrophy) Hypersensitivity Laminitis

[1] Dexamethasone may therefore potentiate the effect of a certain kind of heart medicines (cardiac glycosides)

[2] Increased glycogenesis, worsening of diabetes mellitus and latent diabetes mellitus can be manifested

Except from substitution therapy, corticosteroid treatments always include an over dosage compared to the physiological condition. Adverse effects do not always depend on the size of the dose and the length of the treatment, but also on the individuals' sensitivity.
The individuals own hormone (ACTH- and cortisol) excretion is inhibited and cushingoid symptoms can occur. Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal tract ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs.
The immunosuppressant actions may weaken resistance to or exacerbate existing infections.

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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system:

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

Intramuscular use or slow intravenous infusion.

Species:	Dosage (Intramuscular or slow intravenous infusion)
Horses, cattle,	0,06 mg/kg (3 ml/100 kg)
Pigs	0,06 mg/kg (3 ml/100 kg, dosage can be repeated after 24 to 48 hours)
Dog, cat	0,1 mg/kg (0,5 ml/10 kg, dosage can be repeated after 24 to 48 hours)

9. Advice on correct administration

10. Withdrawal periods

Cattle:	Meat and offal:	8 days
	Milk:	72 hours
Pigs:	Meat and offal:	2 days
Horses:	Meat and offal:	8 days

Not authorized for use in horses producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Store the vial in outer carton in order to protect from light.
Do not use after expiry date stated on carton
Shelf life after first opening the immediate packaging: 8 weeks.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

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> <or> <pharmacist> 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

One vial of 20 ml or 50 ml, in a carton box.Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

2024-11-06

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

Manufacturer responsible for batch release:
Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

<Local representatives <and contact details to report suspected adverse reactions>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>