Dexamethason 4 mg/ml

4 mg/ml solution for injection

Active ingredient: Dexamethasone dihydrogen phosphate disodium

Target species: Horses, pigs, dogs and cats





Name and address of the marketing authorisation holder:
bela-pharm GmbH & Co.KG, Lohner Str. 19, 49377 Vechta - Germany

Statement of the active substance(s) and other ingredient(s):
1.0 ml solution contains:
Pharmacological active substance:
Dexamethasone dihydrogen phosphate disodium 5.24 mg
(equivalent to 4.00 mg Dexamethasone)
Adjuvants:
Benzyl alcohol 9.45 mg

Indications:
Dexamethason 4 mg/ml acts palliatively (supporting) in the therapy of the following diseases in *cattle*, *horse*, *pig*, *dog* and *cat*:
- primary ketosis;
- acute, not infectious inflammations of the articulations, tendons and bursae;
- non-infectious inflammatory or allergic dermatitis.

The indication is to be carefully proved before initiating therapy with dexamethasone.

Contraindications:
Do not use Dexamethason 4 mg/ml in:
- gastro-intestinal ulcera, badly healing wound and ulcera, fractures;
- viral infections, systemic mycosis;
- general immune deficiency;
- glaucoma, cataract;
- osteoporosis, hypocalcaemia;
- hypercorticism;
- hypertension;
- pancreatitis;
- in cattle in the last third of gestation.

Bacterial and parasitic infections must be cured by a suitable treatment prior to therapy with Dexamethason 4 mg/ml.
Relative contra-indications, where special precautions are necessary:
- Diabetes mellitus (control of blood values and increase of insulin-dose, if necessary);
- congestive cardiac insufficiency (careful surveillance);
- chronic renal insufficiency (careful surveillance);
- epilepsy (avoid long-time treatment).

The use of glucocorticoids shall be restricted to careful (strict) indication in:
- growing animals and geriatric patients
- animals with suckling offspring
- pregnant animals, due to the unclarified possible teratogenic effects of dexamethasone,
- equine, as glucocorticoids-induced laminitis may occur as complication.

Considering vaccination, an adequate time period shall be observed between vaccination and therapy with glucocorticoids. An active vaccination shall not be executed concomitantly and two weeks after a therapy with glucocorticoids. The formation of a sufficient immunity may also be influenced in vaccinations given 8 weeks prior to start of therapy.
Do not treat *mares*, from which milk is gained for human consumption.

Adverse reactions:
- suppression of ACTH, reversible atrophy of adrenal cortex based on inactivity;
- immune suppression with increased risk of infections and negative influence on the course of infections;
- retarded healing of wounds and bones, osteoporosis, arthropathy, muscle degeneration, retarded growth with disturbances of bone formation and damage of the bone matrix in young animals;
- diabetogenic effects with decreased glucose-tolerance, steroid-induced Diabetes mellitus and aggravation of existing Diabetes mellitus;
- Cushing-syndrome;
- pancreatitis;
- lowering of the threshold for convulsions, manifestation of a latent epilepsy, euphoria, excitation, occasionally depression in *cats*, in *dogs* depression or aggressiveness in single cases;
- skin atrophy;
- glaucoma, cataract;
- polydipsia, polyphagia, polyuria;
- gastro-intestinal ulcera;
- reversible hepatopathy;
- proneness to thrombosis;
- hypertension;
- retention of sodium with oedema, hypokalaemia, hypocalcaemia;
- induction of birth in *cattle* in the last third of gestation; thereafter increase in retained placenta
- transient reduction in milk performance in cows;
- laminitis in *horses*.

The occurrence of adverse reactions after application of Dexamethason 4 mg/ml should be reported to the national health authorities or the marketing authorisation holder.

Target species
Horse, *cattle*, *pig*, *dog*, *cat*.

Dosage for each species, route(s) and method of administration:
For subcutaneous, intramuscular or intravenous injection.

Cattle, *horse*:	0.02 – 0.06 mg dexamethasone / kg body weight (b.w.) equivalent to 0.25 - 0.75 ml Dexamethason 4 mg/ml per 50 kg b.w.
Pig:	0.04 – 0.06 mg dexamethasone / kg body weight (b.w.) equivalent to 0.1 - 0.15 ml Dexamethason 4 mg/ml per 10 kg b.w.
Dog, *cat*:	0.1 – 0.25 mg dexamethasone / kg body weight (b.w.) equivalent to 0.025 - 0.063 ml Dexamethason 4 mg/ml per kg b.w.

Single use only.

Advice on correct administration:

Special warnings for each target species:

Due to the content of propylenglycol life-threatening shock reactions may occur in rare cases. The solution for injection shall be given slowly and should have almost body temperature. When first signs of introlerance occur, stop the injection immediately and initiate shock therapy, if necessary.

Special precautions for use in animals:

Under therapy with glucocorticoids like Dexamethason 4 mg/ml the course of the infection may aggravate. The animal owner must be informed prior to treatment about this possible adverse effect and asked to inform the veterinarian if this effect occurs.

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

Not indicated.

Use during pregnancy, lactation or lay:

Due to the unclarified possible teratogenic effects of dexamethasone, the application during gestation shall be restricted to careful (strict) indication.

Do not use in cattle in the last third of gestation.

When using during lactation a transient reduction in milk performance may be observed in *cows*.

Use in strict indications only in animals with suckling offspring, as glucocorticoids pass into the milk and growth retardation may be observed in the young animals.

Interaction with other medicinal products and other forms of interaction:

- reduced tolerance to cardiac glycosides due to lack of potassium;
- increased loss of potassium when thiazid- or loop diuretics are given concomitantly;
- increased risk of gastro-intestinal ulcera and gastro-intestinal bleedings when non-steroidal antiphlogistics are given concomitantly;
- reduced efficacy of insulin;
- decreased effect of glucocorticoids at concomitant use of pharmaceuticals inducing enzymatic degradation (e.g. barbiturates);
- increase in intraocular pressure in combined administration of anticholinergics;
- reduced efficacy of anticoagulants;
- suppressive effect on skin reactions in intracutaneous allergy tests.

Overdose:

Following overdose, an increase of adverse effects has to be expected. There is no specific antidote known.

Incompatibilities:

Mixtures with other pharmaceuticals are to be avoided due to possible incompatibilities.

Withdrawal period(s):

Cattle:	edible tissues:	16 days
	milk:	4 days
Pig:	edible tissues:	4 days
Horse:	edible tissues:	16 days

Do not use in mares, from which milk is gained for human consumption.

Special storage precautions:
Store in a refrigerator (2 - 8 °C). .
Keep out of reach and sight of children.
The product should be used up immediately after opening. Remaining quantities are to be wasted.
Do not use after the expiration date stated on the label.

Special warnings:
None.

Special precautions for the disposal of unused product or waste materials:
Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with wastewater or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

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For Veterinary use only.

Available on prescription only!