Dexamethason 4 mg/ml

4 mg/ml solution for injection

for cattle, horses, pigs, dogs and cats

Name and address of the marketing authorisation holder
Bela-Pharm GmbH & Co. KG
Lohner Straße 19
49377 Vechta / Germany

Name of the veterinary medicinal product
Dexamethason 4 mg/ml
4 mg/ml solution for injection for *cattle, horses, pigs, dogs* and *cats*

Statement of the active substance(s) and other ingredient(s)
1.0 ml solution contains:
Active substance:
Dexamethasone dihydrogen phosphate disodium 5.24 mg
(equivalent to 4.00 mg Dexamethasone)
Adjuvants:
Benzyl alcohol 16.67 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 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 the veterinary medicinal product.
Do not use in cases of hypersensitivity to the active substance, to glucocorticoids or to any of the excipients.

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*;
- in very rare occasions hypersensitivity reactions may occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Target species
Horses, cattle, pigs, dogs, and *cats*.

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
None.

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

Keep out of reach and sight of children.
Do not store above 30 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "EXP".
The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days

Special warnings

Special warnings for each target species:
None.
Special precautions for use in animals:
Under therapy with glucocorticoids like this veterinary medicinal product the course of the infection may aggravate. Please consult your veterinarian when an infection occurs.
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 intolerance occur, stop the injection immediately and initiate shock therapy, if necessary.

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.

Special safety precautions to be taken by the person administering the medicinal product to animals:
The veterinary medicinal product may cause allergic reactions. People with known hypersensitivity to dexamethasone should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Dexamethason may have negative effects on fertility or the unborn child.

To avoid the risk of self-injection, pregnant woman shall not handle the veterinary medicinal product. The veterinary medicinal product may cause irritation to eyes and skin. Avoid skin and eye contact. In the case of accidental skin- or eye contact rinse with plenty of water. Seek medical advice if irritation persists. Wash hands after use.

Use during pregnancy, lactation or lay:
Pregnancy:
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.
Lactation:
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;
- pronounced muscle weakness in patients suffering from Myasthenia gravis when given in combination with an anticholinergic (e.g. neostigmine).

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.

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.

Date on which the package leaflet was last approved
20.06.2019

Other information
50 ml

Marketing authorisation number: 6933074.00.00 (Germany)

For Veterinary use only. Available on prescription only!

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