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Dechra Veterinary Products

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Rapidexon® 2 mg/ml Solution for Injection

Species: Cats, Cattle, Dogs, Horses only, Pigs

Therapeutic indication:Pharmaceuticals: Anti-inflammatory preparations: Injections: Steroids

Active ingredient: Dexamethasone

Product: Rapidexon® 2 mg/ml Solution for Injection

Product index: Rapidexon 2 mg/ml Solution for Injection

Cattle - milk:72 hours

Cattle - meat:8 days

Pig - meat:2 days

Withdrawal notes: Horse - meat: 8 days. Not authorised for use in horses producing milk for human consumption.

Incorporating:

Qualitative and quantitative composition

Each ml contains:

Active substance:

Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 mg

Excipients:

Benzyl alcohol (E1519) 15.0 mg

Sodium chloride

Sodium citrate dihydrate

Citric acid monohydrate

Sodium hydroxide

Water for injections

Pharmaceutical form

Solution for injection. A clear colourless solution practically free from particles.

Clinical particulars

Target species

Horses, cattle, pigs, cats and dogs.

Indications for use for each target species

In horses, cattle, pigs, dogs and cats:

Treatment of inflammatory or allergic conditions.

In cattle:

Treatment of primary ketosis (acetonaemia).

Induction of parturition.

In horses:

Treatment of arthritis, bursitis or tenosynovitis.

Contraindications

Except in emergency situations, do not use in animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency, hyperadrenocorticism, or osteoporosis.

Do not use in viral infections during the viraemic stage or in cases of systemic mycotic infections.

Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis.

Do not administer intra-articularly where there is evidence of fractures, bacterial joint infections and aseptic bone necrosis.

Do not use in cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.

Refer to *Use during pregnancy, lactation or lay*.

Special precautions for safe use in the target species

If the veterinary medicinal product is used for induction of parturition in cattle, then a high incidence of retained placentae may be experienced and possible subsequent metritis and/or subfertility. Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

Use of corticosteroids in horses has been reported to induce laminitis. Therefore horses treated with such preparations should be monitored frequently during the treatment period.

Because of the pharmacological properties of the active ingredient, special care should be taken when the veterinary medicinal product is used in animals with a weakened immune system.

Except in cases of acetonaemia and induction of the parturition, corticoid administration is to induce an improvement in clinical signs rather than a cure. The underlying disease should be further investigated. When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper.

Following intra-articular administration, use of the joint should be minimized for one month and surgery on the joint should not be performed within eight weeks of use of this route of administration.

Only the 25 ml vial should be used to treat cats, dogs and small piglets to prevent excessive puncturing of the closure.

See *Adverse events*.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.

The veterinary medicinal product should not be administered by pregnant women.

Special precautions for the protection of the environment

Not applicable.

Adverse events

Horses, cattle, pigs, dogs, cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Polydipsia2, polyphagia2
	Polyuria2
	Hypokalaemia3, changes in blood bioch
	haematological parameters, hyperglyca
	Hepatomegaly6
	Pancreatitis7
	Laminitis

Undetermined frequency (cannot be estimated from the available data)	**Iatrogenic hyperadrenocorticism (Cushing's water retention3**
	Cutaneous calcinosis
	Delayed wound healing, weakened resistanc infections4
	Gastrointestinal ulceration5
	Retained placenta, metritis, subfertility
	Milk production decrease

1 Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g., redistribution of body fat, muscle weakness and wastage and osteoporosis may result.

2 After systemic administration and particularly during early stages of therapy.

3 Upon long-term use.

4 In the presence of bacterial infection, antibacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.

5 May be exacerbated in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

6 With increased serum hepatic enzymes.

7 Increased risk of acute pancreatitis.

8 Transient.

Corticosteroids are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe adverse reactions with long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control clinical signs.

During therapy effective doses suppress the hypothalamo-pituitreal adrenal axis. Following cessation of treatment, signs of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment (for further information see standard texts).

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 its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not administer the veterinary medicinal product in pregnant females, except where the intention is to induce parturition. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy is likely to cause abortion or early parturition in ruminants and may have a similar effect in other species.

Use of the veterinary medicinal product in lactating cows may cause a reduction in milk yield.

Refer to *Special precautions for use in animals*.

Interaction with other medicinal products and other forms of interaction

Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.

Because corticosteroids can reduce the immunoresponse to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination.

Administration of dexamethasone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.

Concurrent use with anticholinestaerase may lead to increased muscle weakness in patients with myasthenia gravis.

Glucocorticoids antagonise the effects of insulin.

Concurrent use with phenobarbital, phenytoin and rifampicin can reduce the effects of dexamethason.

Amounts to be administered and administration route

Horses: Intravenous, intramuscular, intraarticular, intrabursal or local use.

Cattle, pigs, dogs and cats: Intramuscular use.

For the treatment of inflammatory or allergic conditions the following average doses are advised. However the actual dose used should be determined by the severity of the signs and the length of time for which they have been present.

Horses, cattle and pigs: 0.06 mg/kg body weight corresponding to 1.5 ml/50 kg

Dogs and cats: 0.1 mg/kg body weight corresponding to 0.5 ml/10 kg

For the treatment of primary ketosis in cattle (acetonaemia):

0.02 to 0.04 mg/kg body weight corresponding to 5-10 ml per cow given by intramuscular injection is advocated dependent on the size of the cow and the duration of the signs. Care should be taken not to overdose Channel Island breeds. Larger doses will be required if the signs have been present for some time or if relapsed animals are being treated.

For the induction of parturition:

0.04 mg/kg body weight corresponding to 10 ml per cow as a single intramuscular injection after day 270 of pregnancy.

Parturition will normally occur within 48-72 hours.

For the treatment of arthritis, bursitis or tenosynovitis: by single intra-articular, intrabursal or local injection in the horse: Dosage 1-5 ml.

These quantities are not specific and are quoted purely as a guide. Injections into joint spaces or bursae should be preceded by the removal of an equivalent volume of synovial fluid. Strict asepsis is essential.

To measure small volumes of less than 1 ml a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

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

An overdose can induce drowsiness and lethargy in horses. Refer to *Adverse events*.

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.

Withdrawal periods

Cattle Meat and offal: 8 days

Milk: 72 hours

Pigs Meat and offal: 2 days

Horses Meat and offal: 8 days.

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

Pharmacological particulars

Pharmacotherapeutic group: corticosteroid for systemic use, glucocorticoid.

ATCvet code: QH02AB02

Pharmacodynamic properties

This preparation contains the sodium phosphate ester of dexamethasone, a fluoro-methyl derivative of prednisolone, which is a potent glucocorticoid with minimal mineralocorticoid activity. Dexamethasone has ten to twenty times the anti-inflammatory activity of prednisolone. Corticosteroids suppress the immunologic response by inhibition of dilatation of capillaries,

migration and function of leucocytes and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis.

Pharmacokinetic properties

Following intramuscular injection this soluble ester of dexamethasone is readily absorbed and hydrolysed to the parent alcohol giving a prompt response which is maintained for approximately 48 hours. Tmax in cattle, horses, pigs and dogs is reached within 20 minutes following intramuscular administration. T½ varies per species between 5 and 20 hours. Bioavailability after intramuscular administration is almost 100%. Dexamethasone has a medium duration of activity.

Pharmaceutical particulars

Major incompatibilities

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

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale in 50 ml and 100 ml vials: 2 years.

Shelf life of the veterinary medicinal product as packaged for sale in 25 ml vials: 18 months.

Shelf life after first opening the immediate packaging: 28 days.

Special precautions for storage

Do not store above 25°C.

Do not freeze.

Keep the vial in the outer carton.

Immediate packaging

Vial:

* Volume 25 ml (filled in 30 ml vial), 50 ml and 100 ml.

* Glass type I; quality Ph.Eur.

* Uncoloured.

Stopper:

* Bromobutyl rubber stopper type I.

* Secured with aluminium cap.

Not all pack sizes may be marketed.

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 .

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.

Marketing Authorisation Holder (if different from distributor)

Eurovet Animal Health BV, Handelsweg 25, 5531 AE Bladel, The Netherlands.

Marketing Authorisation Number

GB: Vm 16849/4007

NI: VM 16849/3012

Significant changes

Date of the first authorisation or date of renewal

21 February 2006

Date of revision of the text

January 2025

Any other information

For animal treatment only. To be supplied only on veterinary prescription. Keep out of the sight and reach of children.

Legal category

Legal category:POM-V

GTIN

GTIN description: Rapidexon 2 mg/ml Solution for Injection 50 ml:

GTIN:08714225159413

GTIN description: Rapidexon 2 mg/ml Solution for Injection 100 ml:

GTIN:08714225159420