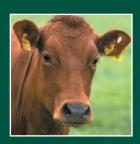
# Rapidexon®





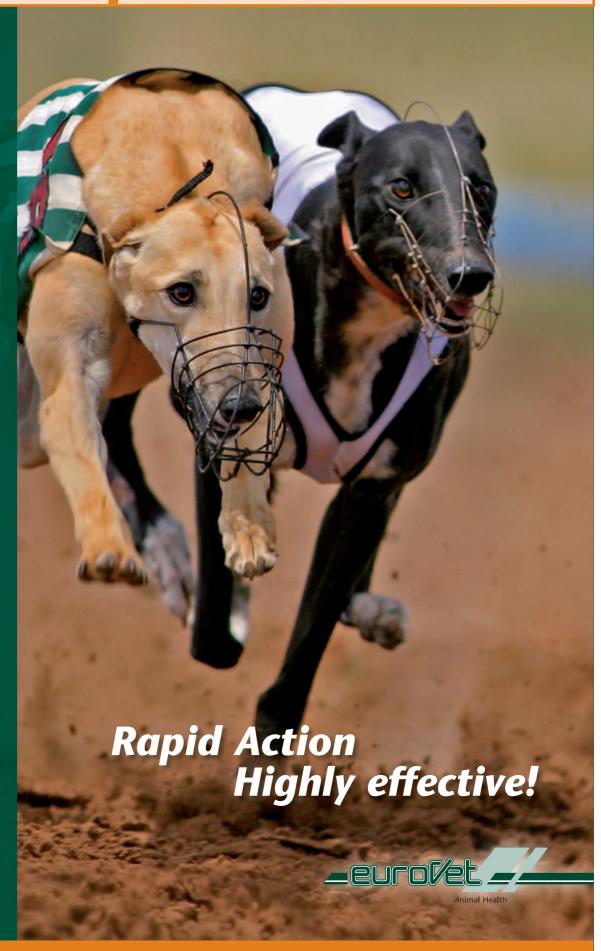






Multiple indications

Short withdrawal period



## **Dexamethasone sodium phosphate**

Rapidexon is a solution for injection and contains dexamethasone as an active substance; a known and trusted active ingredient with proven effectiveness. The concentration is 2,0 mg/ml dexamethasone as dexamethasone sodium phosphate.

# **Rapid action - highly effective**

Rapidexon<sup>®</sup> contains the sodium phosphate ester of dexamethasone. This water soluble ester ensures a fast intake and intense effect. Following intramuscular injection in cattle, pig, horse, cat and dog, the optimal plasma level is reached within minutes.

Mormede P., (Ann.Rech.Vet, 1980, 11(2), 157 - 164) stated that the soluble esters of dexamethasone (phosphate) have a fast and intense activity, but for a short period of time. The insoluble esters (isonicotinate, acetate, terethoxyacetate) have a less intense but longer action. The macro crystalline suspensions of isonicotinate are depot forms with a very long action.

The dosage - effect relation of dexamethasone phosphate is not linear after an intravenous application. As from the lowest tested amount (38 µg/kg as dexamethasone alcohol, or half the therapeutic amount) a maximum therapeutic activity is obtained. Increase of the doses extends only the action but remains less than 24 hours, even for the highest dosage (152 μg/kg as dexamethasone alcohol).

# **Multiple indications**

Rapidexon<sup>®</sup> is registered for the use in cattle, pig, horse, dog and cat, for the treatment of inflammatory and allergic conditions. Extra indications are:

Cattle: for the treatment of primary ketosis and induction of calving for the treatment of inflammation of joints, bursas, tendons and

tendon sheaths



**RAPIDEXON** 

Rapid action!

# Dosage for each species, route and method of administration

(applicable in the European Union)

For intravenous, intramuscular, intraarticular, local or intrabursal administration in horses. For intramuscular injection in cattle, pigs, dogs and cats.

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.

Species	Dosage
Horses, cattle, pigs	0.06 mg/kg body weight corresponding to 1.5 ml/50 kg
Dog, cat	0.1 mg/kg body weight corresponding to 0.5 ml/10 kg

Doses may be repeated once at 24-48 hour intervals if required. Injection sites should be alternated.

## For the treatment of primary ketosis in cattle

0.02 to 0.04 mg/kg body weight corresponding to 5-10 ml per cow given by intramuscular injection is recommended 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. In most early cases a single dose will effect a cure but the dose may be repeated at 48 hour intervals if necessary.

## For the induction of calving.

0.04 mg/kg body weight corresponding to 10 ml per cow as a single intramuscular injection after day 270 of pregnancy. Calving will normally occur within 48-72 hours. If calving does not occur within these periods the dose may be repeated.

<u>For the treatment of inflammation of joints, bursas or tendon(sheath)s</u> 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.

# **Short withdrawal period**

Rapidexon® has very short withdrawal period for both meat and milk (in EU).

Cattle: meat: 7 days

milk: 72 hours

Pig: meat: 2 days Horse: meat: 11 days

#### PRODUCT INFORMATION (AS EXAMPLE UK REGISTRATION)

## RAPIDEXON® 2 MG/ML, SOLUTION FOR INJECTION

#### STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml contains:

Active substance:
Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 mg

Benzyl alcohol, (E1519)
A clear colourless solution practically free from particles 15.0 ma

TARGET SPECIES
Horses, cattle, pigs, cats and dogs.

#### INDICATION(S)

In horses, cattle, pigs, dogs and cats: Dexamethasone may be used for the treatment of inflammatory and allergic conditions.

In cattle: Treatment of primary ketosis. Induction of calving.

In horses: Treatment of inflammation of joints, bursas or tendon(sheath)s.

# DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intravenous, intramuscular, intraarticular, local or intrabursal administration in horses.

For intramuscular injection in cattle, pigs, dogs and cats.

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.

Species	Dosage
Horses, cattle, pigs	0.06 mg/kg body weight corresponding to 1.5 ml/50 kg
Dog, cat	0.1 mg/kg body weight corresponding to 0.5 ml/10 kg

Doses may be repeated once at 24-48 hour intervals if required. Injection sites should be alternated

For the treatment of primary ketosis in cattle 0.02 to 0.04 mg/kg body weight corresponding to 5-10 ml per cow given by intramuscular injection is recommended 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. In most early cases a single dose will effect a cure but the dose may be repeated at 48 hour intervals if necessary.

For the induction of calving 0.04 mg/kg body weight corresponding to 10 ml per cow as a single intramuscular injection after day 270 of pregnancy. Calving will normally occur within 48-72 hours. If calving does not occur within these periods the dose may be repeated.

For the treatment of inflammation of joints, bursas or tendon(sheath)s 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.

Except in emergency situations, do not use in animals suffering from diabetes, kidney insufficiency, heart insufficiency, Cushing's syndrome or osteoporosis

or osteoporosis.

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

Do not use in animals suffering from gastrointestinal ulcers or ulcers of the cornea, or demodicosis.

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

Do not use in known cases of hypersensitivity to the active substance, to corticosteroids and to any other ingredient of the product.

#### ADVERSE REACTIONS

ADVENSE REACTIONS

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.

Steroids themselves, during treatment, may cause introgenic hyper.

control clinical signs.

Steroids themselves, during treatment, may cause iatrogenic hyperadrenocorticism (Cushings disease) symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness and wastage and osteoporosis may result.

During therapy effective doses suppress the interaction between the hypothalamus, pituitary gland and adrenal gland cortex. 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).

following the withdrawal of treatment, (for further information see standard texts).

Systemically administered corticosteroids may cause polyuria (large volume of urine), polydipsia (thirst) and polyphagia (hunger), particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia (low potassium in the blood) in long term use. Systemic corticosteroids have caused deposition of calcium in the skin.

tion of calcium in the skin.

Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, concurrent antibacterial therapy is usually required. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids and g.i.t. ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

Corticosteroid use may cause enlargement of the liver with increased

Corticosteroid use may cause enlargement of the liver with increased serum liver enzymes and may increase the risk of acute pancreatitis. Other possible adverse reactions associated with corticosteroid use include changes in blood biochemical and haematological parameters.

Transient hyperglycaemia can occur. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

### ADVICE ON CORRECT ADMINISTRATION

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

WITHDRAWAL PERIOD

Cattle meat and offal: 7 days 72 hours

Pig meat and offal: 2 days

Horses meat and offal: 11 days

## **SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C. Do not freeze. Keep vial in the outer carton. Keep out of reach and sight of children. Do not use after the expiry date which is stated on the label and carton after EXP Shelf-life after first opening the immediate packaging: 28 days

### Additional information is available upon request.





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