Equipalazone® 1 g Oral Paste

Introduction

Company name: Dechra Veterinary Products Limited

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Presentation

1 unit dose contains: Active substance:

Phenylbutazone 1 g, 16.66% w/w

Excipients: Sodium methyl parahydroxybenzoate 0.006 g, 0.10% w/w

Sodium propyl parahydroxybenzoate 0.0015 g, 0.025% w/w

Also contains sucrose, tragacanth, glycerol, hexaflavour vanilla, butterscotch flavour, purified water.

Oral paste. Off white paste pre-filled into 32 ml syringes.

Uses

Indicated in the treatment of musculoskeletal disorders in horses and ponies where the anti-inflammatory and analgesic properties of phenylbutazone can offer relief, for example, in lameness associated with osteoarthritic conditions, acute and chronic laminitis, bursitis and carpitis.

Dosage and administration

Each marked division (2 turns of the ring) is equivalent to 1 unit dose (i.e. 1 g phenylbutazone).

Horses: 450 kg (1000 lb) body weight:

2 unit doses twice on day one (equivalent to 8.8 mg/kg/day), 1 unit dose twice daily for four days (i.e. 4.4 mg/kg/day) followed by 1 unit dose daily or on alternate days (i.e. 2.2 mg/kg/day), sufficient to keep the horse comfortable.

Ponies: 225 kg (500 lb) body weight:

1 unit dose (i.e. 4.4 mg/kg) on alternate days.

Remove cap from nozzle. Turn ring to required dosage. Express dose as near to the back of the tongue as possible. Replace cap after use. Store in a cool place.

Adjust dose according to body weight.

Discontinue treatment if no response is evident after four to five days treatment.

Avoid the introduction of contamination during use.

Contraindications, warnings, etc

The therapeutic index of phenylbutazone is low.

Do not exceed the stated dose or duration of treatment.

Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia or hypersensitivity to the product.

Do not administer other NSAIDs concurrently or within 24 hours of each other.

Special warnings for each target species: Discontinue treatment if no response is evident after four or five days treatment.

The clinical effect of phenylbutazone can be evident for at least three days following cessation of administration. This should be borne in mind when examining the horse for soundness.

Special precautions for use in animals: Use in animals less than six weeks of age, or in aged animals, may involve additional risks. If such use cannot be avoided, animals may require a reduced dosage and special clinical management.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal as there is a risk of increased toxicity.

It is preferable that NSAIDs which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.

Response to long term therapy should be monitored at regular intervals by a veterinary practitioner.

Dosage should be discontinued in animals developing gastrointestinal or vascular disorders, oral ulceration or inappetance during treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals: The product should be handled with care at all times to reduce the risk of accidental ingestion or skin contact. If accidental skin or eye contact occurs, the site should be washed immediately with water. If the product is ingested, seek medical advice immediately and show the product packaging.

Advice to doctors: gastric lavage (emesis in children) should be performed urgently. Charcoal haemoperfusion has also been shown to be beneficial. Treatment should then be administered symptomatically.

Other precautions: Some authorities (including the Jockey Club) regard phenylbutazone as a "prohibited substance" under the rules of competition. Therefore, use of this product in a competition horse should be in accordance with the recommendations/advice of the relevant competition authorities.

Adverse reactions: Non-steroidal anti-inflammatory drugs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.

Use during pregnancy and lactation: The safety of phenylbutazone in pregnancy has not been established. Use during pregnancy should be avoided whenever possible, particularly during the first trimester.

Interactions: Some non-steroidal anti-inflammatory drugs may be highly bound to plasma proteins and compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.

Concurrent administration of potentially nephrotoxic drugs (e.g. aminoglycoside antibiotics) should be avoided.

It is preferable that NSAIDs which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.

Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.

Overdose: The therapeutic index of phenylbutazone is low. In man, charcoal haemoperfusion in conjunction with dopamine has been used to treat overdosage. There is no experience of this technique in the horse.

Withdrawal period: Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

Incompatibilities: None known.

Pharmaceutical precautions

Do not store above 25°C. Any contents remaining later than 28 days after the first opening should be discarded. Replace cap after use. Do not use after the expiry date stated on the label after EXP.

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

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

Disposal: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Legal category

POM-V

Packaging quantities

32 ml high-density polyethylene dial a dose syringe containing 6 unit doses (6 g phenylbutazone) per syringe.

Further information

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

Manufacturer responsible for batch release: Dales Pharmaceuticals, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW.

Date of last review: 15.12.2010

Marketing authorisation holder (if different from distributor)

Dechra Limited, Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW.

Marketing authorisation number

Vm 10434/4006.

GTIN (Global Trade Item No)

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