Equipalazone 1g®

Oral Powder

UK IE

Marketing authorisation holder:
Dechra Limited,
Snaygill Industrial Estate,
Keighley Road, Skipton,
North Yorkshire,
BD23 2RW, United Kingdom

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

Name of the veterinary medicinal product: Equipalazone 1 g oral powder. Phenylbutazone.

Statement of the active substance and other ingredients:

Each sachet contains 1 g phenylbutazone. Oral powder. White/cream powder.

Indications: Equipalazone 1 g oral powder is 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, and in the reduction of post-surgical soft tissue reaction.

Contraindication: The therapeutic index of phenylbutazone is low. Do not exceed the stated dose or the duration of treatment.

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

Do not use 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.

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.

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

Target species: Horses and ponies.

Dosage for each species, route and method of administration:

For oral administration only. Dependent on individual response, but as a guide:

Horses: 450 kg (1000 lb) body weight: two sachets to be administered twice on day one (equivalent to 8.8 mg/kg/day) followed by one sachet twice daily for four days (4.4 mg/kg/day), then one sachet daily or on alternate days sufficient to keep the horse comfortable (2.2 mg/kg/day).

Ponies: 225 kg (500 lb) body weight: one sachet (4.4 mg/kg/day) on alternate days. Adjust dose according to body weight. Discontinue treatment if no response is evident after four to five days treatment.

Advice on correct administration: For ease of administration mix the powder with a small quantity of feed. It should only be mixed with dry foodstuffs, to prevent premature solution of the encapsulation coat.

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.

Special storage precautions: Keep out of the sight and reach of children. Do not store above 25°C. Store in a dry place. Do not use this veterinary medicinal product after the expiry date which is stated on the sachet and carton after EXP.

Special warnings: Special warnings for each target species:

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 horses for soundness.

Special precautions for use in animals:

Use in any animal less than six weeks of age, or in aged animals, may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful 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.

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, skin contact or dust inhalation. 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.

Use during pregnancy or lactation:

The safety of phenylbutazone in pregnancy has not been established.

Use during pregnancy should be avoided whenever possible, particularly during the first trimester.

Interaction with other medicinal products and other forms of interaction:

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

Some NSAIDs 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 should be avoided.

Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given NSAIDs.

Overdose (symptoms, emergency procedures, antidotes):

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

Special precautions for the disposal of unused product or waste materials: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with national requirements.

Date on which the package leaflet was last approved: March 2015

Other information: 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.

When mixed with a concentrate feed, the product was shown to be palatable to horses.

UK: Vm 10434/4005 POM-V Prescription Only Medicine - Veterinarian	IE: VPA 10799/005/001 POM Prescription Only Medicine

For animal treatment only. To be supplied only on veterinary prescription.

Veterinary medicinal product authorised for use in UK and IE.

Package quantities: boxes of 32 and 100 sachets. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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