Dechra Veterinary Products

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Equipalazone® Original 1 g Oral Powder

Species: Horses only

Therapeutic indication:Pharmaceuticals: Anti-inflammatory preparations: Oral: Horse NSAIDs

Active ingredient: Phenylbutazone

Product: Equipalazone® Original 1 g Oral Powder

Product index: Equipalazone Original 1 g Oral Powder

Withdrawal notes: 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.

Incorporating:

Qualitative and quantitative composition

Each sachet contains:

Active substance:

Phenylbutazone 1 g

Excipients:

Acacia

Gelatin

Silicon dioxide

Pharmaceutical form

Oral powder. White/cream powder.

Clinical particulars

Target species

Horses and ponies (non-food producing).

Indications for use for each target species

For the treatment of musculoskeletal disorders in horses and ponies where the anti-inflammatory and analgesic properties of phenylbutazone can offer relief. Examples of conditions normally considered suitable for treatment with phenylbutazone include lameness associated with osteoarthritic conditions, acute and chronic laminitis, bursitis and carpitis, and in the reduction of post-surgical soft tissue reaction.

Contraindications

Do not administer with other non-steroidal anti-inflammatory drugs (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.

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

Special warnings

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 safe use in the target species

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

Use in any animal under 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.

NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.

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

The veterinary medicinal 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 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.

Special precautions for the protection of the environment

Not applicable.

Adverse events

Horses and ponies (non-food producing):

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(1 to 10 animals / 10,000 animals treated): Renal

* In common with other NSAIDs that inhibit prostaglandin synthesis, there may be gastric and/or renal intolerance. This is usually associated with overdosage. Recovery is usual on cessation of treatment and following the initiation of supportive symptomatic therapy (see *Symptoms of overdose*).

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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 the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product in pregnancy has not been established.

Pregnancy:

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

Interaction with other medicinal products and other forms of interaction

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 potential nephrotoxic drugs (e.g. aminoglycoside antibiotics) should be avoided.

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

Amounts to be administered and administration route

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

The dosage should be adjusted according to the individual animal's response, but the following may be taken as a guide:

Horses 450 kg (1000 lb) body weight: the contents of two sachets to be administered twice on day 1 of treatment (equivalent to 8.8 mg/kg/day) followed by the contents of 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) on alternate days.

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

For ease of administration mix the powder with a small quantity of feed.

Dampening of the veterinary medicinal product in feed 5 minutes prior to feeding has been shown to have no detrimental influence on the palatability of the veterinary medicinal product. However, the influence of prolonged dampening on palatability or stability of the veterinary medicinal product is not known.

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

Overdosing may result in gastric and large intestinal ulceration and general enteropathy. Renal papillary damage may also occur with impaired renal function. Subcutaneous oedema, especially under the jaw may become evident due to plasma protein loss.

There is no specific antidote. If signs of possible overdosage occur, treat the animal symptomatically.

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 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

Not authorised for use 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.

Pharmacological particulars

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids.

ATCvet code: QM01AA01

Pharmacodynamic properties

Phenylbutazone acts by inhibiting the production of prostaglandins. Prostaglandins possess a wide variety of physiological properties, including those involved in the production of pain, inflammation and pyrexia. The main metabolite, oxyphenbutazone, possesses similar pharmacological properties.

Pharmacokinetic properties

Phenylbutazone is generally well absorbed following oral administration. The rate, but not the extent, of absorption may be affected due to binding of phenylbutazone to food and the contents of the gastrointestinal tract. Therefore, it is recommended that the veterinary medicinal product is administered mixed with a small amount of bran or oats.

Phenylbutazone is highly bound to plasma proteins.

Pharmaceutical particulars

Major incompatibilities

None known.

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

Special precautions for storage

Do not store above 25°C.

Store in a dry place.

Immediate packaging

Sachets of a paper/polyethylene outer layer and aluminium/polyethylene inner layer in a cardboard box. Each sachet contains 1.5 g of powder.

Pack sizes: 32 or 100 sachets.

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.

NOAH Compendium

Marketing Authorisation Holder (if different from distributor)

Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom.

Marketing Authorisation Number

GB: VM 50406/5043

NI: VM 50406/3038

Significant changes

Date of the first authorisation or date of renewal

26 August 1994

Date of revision of the text

May 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: Equipalazone Original 1 g Oral Powder 32 sachets:

GTIN:05701170427196

GTIN description: Equipalazone Original 1 g Oral Powder 100 sachets:

GTIN:05701170427202