SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 1 g oral powder for horses and ponies

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Active substance:

Phenylbutazone 1 g

Excipients:

Qualitative composition of excipients and other constituents
Acacia
Gelatin
Silicon dioxide
Sucralose (E955)
Apple flavour

White/cream powder.

3. CLINICAL INFORMATION

3.1 Target species

Horses and ponies (non-food producing).

3.2 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.

3.3 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.

3.4 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.

3.5 Special precautions for use

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.

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

The veterinary medicinal product may cause hypersensitivity (allergic) reactions in those sensitized to phenylbutazone, either via skin contact or accidental inhalation.

People with known hypersensitivity to phenylbutazone, or any of the excipients, should avoid contact with this veterinary medicinal product.

If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes, or difficulty breathing, are more serious symptoms and require urgent medical attention.

This veterinary medicinal product can be irritating to the skin and eyes. Avoid contact with the eyes. In case of accidental eye contact, rinse eyes with plenty of water. If irritation persists seek medical advice. Wash any exposed skin and hands after use.

Care should be taken to avoid ingesting the powder. In the event of accidental ingestion, seek medical advice and show the veterinary medicinal product packaging to the physician.

The safety of phenylbutazone in pregnancy has not been established. The veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses and ponies (non-food producing):

Rare (1 to 10 animals / 10,000 animals treated):	Gastric intolerance* Renal disorder*

* 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 3.10 for further information).

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.

3.7 Use during pregnancy, lactation or lay

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

Pregnancy and lactation:
Use during pregnancy should be avoided whenever possible, particularly during the first trimester.
Use phenylbutazone in pregnant and lactating mares only according to a benefit/risk assessment by the responsible veterinarian.

3.8 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.

Adverse reactions caused by phenylbutazone are exacerbated by concurrent administration of glucocorticoids, other non-steroidal antiphlogistics, or anticoagulants.

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

3.9 Administration routes and dosage

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.

3.10 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.

3.11 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.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AA01.

4.2 Pharmacodynamics

Phenylbutazone is a pyrazolone non-steroidal anti-inflammatory drug (NSAID) which acts by the nonselective inhibition of prostaglandin synthetases (cyclooxygenases COX-1 and COX-2). 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.
Store in a dry place.

5.4 Nature and composition of 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 50406/3019

8. DATE OF FIRST AUTHORISATION

15 June 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

February 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall
Approved: 25 February 2025