1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 1 g oral paste

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each unit dose contains:

Active substance:

Phenylbutazone 1.00 g

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sucrose	
Tragacanth	
Glycerol	
Sodium methyl parahydroxybenzoate	0.006 g
Sodium propyl parahydroxybenzoate	0.0015 g
Hexaflavour vanilla	
Butterscotch flavour	
Purified water	

Off white paste prefilled into 32 ml syringes.

3. CLINICAL INFORMATION

3.1 Target species

Horses and ponies (non-food producing).

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastrointestinal ulceration or bleeding, and where there is evidence of a blood dyscrasia.

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

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

3.4 Special warnings

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

Discontinue treatment if no response is evident after four to 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 horses for soundness.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Dosage should be discontinued in animals developing gastro-intestinal 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 veterinary medicinal 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. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

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.

3.6 Adverse events

Horses and ponies (non-food producing):

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.

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

Pregnancy:
The safety of the veterinary medicinal product has not been established in pregnancy.
Use during pregnancy should be avoided whenever possible, particularly during the first trimester.

3.8 Interaction with other medicinal products and other forms of interaction

Some non-steroidal anti-inflammatory agents 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.

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.

3.9 Administration routes and dosage

Oral use.

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

Horses 450 kg (1000 lb): 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): 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. Discontinue treatment if no response is evident after four to five days.

Avoid the introduction of contamination during use.

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

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.

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 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.

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

5.3 Special precautions for storage

Do not store above 25 ºC.
Replace cap after use.

5.4 Nature and composition of immediate packaging

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

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(S)

VPA22622/007/001

8. DATE OF FIRST AUTHORISATION

01/10/2005

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

05/11/2024

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).