

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF VETERINARY MEDICINAL PRODUCT**

Equipalazone 1 g Oral Paste

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<u>Active substance</u>	<u>Per unit dose</u>
Phenylbutazone	1.00 g
<u>Excipients</u>	
Sodium Methyl Parahydroxybenzoate	0.006 g
Sodium Propyl Parahydroxybenzoate	0.0015 g

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Oral paste.  
Off white paste prefilled into 32 ml syringes.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Horses and ponies.

#### **4.2 Indications for use, specifying the 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 carpalis.

#### **4.3 Contraindications**

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, and 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.

#### **4.4 Special warnings for each target species**

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.

#### **4.5 Special precautions for use**

##### **i. Special precautions for use in animals**

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 gastrointestinal or vascular disorders, oral ulceration or inappetance during treatment.

##### **ii. 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.

iii. 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.

#### **4.6 Adverse reactions (frequency and seriousness)**

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.

#### **4.7 Use during pregnancy, lactation or lay**

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

#### **4.8 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.

#### **4.9 Amounts to be administered and administration route**

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.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

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.

#### **4.11 Withdrawal periods**

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.

### **5. PHARMACOLOGICAL PARTICULARS**

Phenylbutazone is a pyrazolone non-steroidal anti-inflammatory, analgesic and antipyretic agent.

**ATC Vet Code:** QM01AA01

## **5.1 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.

## **5.2 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. Phenylbutazone is highly bound to plasma proteins.

## **6. PHARMACOLOGICAL OR IMMUNOLOGICAL PROPERTIES**

### **6.1 List of excipients**

Sucrose  
Tragacanth  
Glycerol  
Sodium methyl parahydroxybenzoate  
Sodium propyl parahydroxybenzoate  
Hexaflavour vanilla  
Butterscotch flavour  
Purified water

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

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

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

### **6.4 Special precautions for storage**

Do not store above 25°C.  
Replace cap after use.

**6.5 Nature and contents of immediate packaging**

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

**6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

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

**7. MARKETING AUTHORISATION HOLDER**

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

**8. MARKETING AUTHORISATION NUMBER**

Vm 10434/4006

**9. DATE OF FIRST AUTHORISATION**

26 August 1994

**10. DATE OF REVISION OF THE TEXT**

July 2022

Approved 12 July 2022



