# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 200 mg/ml Solution for Injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**
Phenylbutazone 200 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Benzyl alcohol | 0.015 ml |
| Sodium hydroxide | |
| Water for injection | |

Clear, colourless to pale yellow solution.

## 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 against inflammation, pain and lameness (for example, osteoarthritis, acute and chronic laminitis, bursitis and carpitis).

### 3.3 Contraindications

Do not administer with other non-steroidal anti-inflammatory agents 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; where there is evidence of a blood dyscrasia or of hypersensitivity to the product.

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 the 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 non-steroidal anti-inflammatory drugs, 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 should be handled with care at all times to reduce the risk of accidental ingestion, skin contact or self-injection.

If accidental skin or eye contact occurs, the site should be washed immediately with water. If the product is self-injected or 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.

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):

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Collapse[a] |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Injection site reaction[b] |

[a] following intravenous injection. The product should be injected slowly over as long a period as is reasonably practical. At the first signs of intolerance, the administration of the injection should be interrupted.
[b] if the injection is accidentally inoculated under the skin during intravenous administration.

Non-steroidal anti-inflammatory drugs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infection, 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

The safety of the veterinary medicinal product has not been established during pregnancy. The compound has been shown to have no effect on initiation or regularity of the oestrus cycle in the mare.

Pregnancy:
Phenylbutazone has been shown to cross the placenta.

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.

Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.

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

## 3.9 Administration routes and dosage

Intravenous use.

Horses 450 kg (1000 lb) bodyweight: Maximum 10 ml (4.4 mg phenylbutazone/kg).

Ponies 225 kg (500 lb) bodyweight: Maximum 5 ml (4.4 mg phenylbutazone/kg).

To be administered by very slow intravenous injection in a single dose, which may be followed if necessary by oral phenylbutazone therapy commencing 24 hours after the injection.

In acute cases and in hospitalised animals it may be administered once daily for not more than five consecutive days.

Observe aseptic conditions.

## 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 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, analgesic and antipyretic agent. 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

The serum half-life is dose-dependent and ranges from 3.5 – 6 hours. Therapeutic efficacy may, however, last more than 24 hours, probably due to irreversible binding of phenylbutazone to cyclooxygenase. Phenylbutazone is nearly completely metabolised, primarily to oxyphenbutazone (pharmacologically active) and hydroxyphenbutazone. Oxyphenbutazone has been detected in the urine for up to 48 hours after a single administration. Phenylbutazone is more rapidly excreted into alkaline than acidic urine.

## 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

Store in a refrigerator (2 °C – 8 °C).
Protect from light.

### 5.4 Nature and composition of immediate packaging

Cardboard box containing a 50 ml type I amber glass vial with a bromobutyl rubber stopper and aluminium cap.

### 5.5 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.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited

## 7. MARKETING AUTHORISATION NUMBER

Vm 10434/4007

## 8. DATE OF FIRST AUTHORISATION

26 August 1994

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

March 2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

*Gavin Hall*
Approved: 04 April 2025