SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Equipalazone 200 mg/ml Solution for Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Phenylbutazone	200 mg/ml

Excipients

Benzyl Alcohol	0.015 ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless to pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses and ponies.

4.2 Indications for use, specifying the 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).

4.3 Contraindications

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

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.

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 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.

(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, 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.

(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 infection, appropriate concurrent antimicrobial therapy should be instigated.

There is a risk of irritancy if the injection is accidentally inoculated under the skin during intravenous administration.

Rarely, collapse following intravenous injection has been reported. 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.

4.7 Use during pregnancy, lactation or lay

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

Phenylbutazone has been shown to cross the placenta.

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.

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.

4.9 Amounts to be administered and administration route

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.

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 successfully to treat overdosage with phenylbutazone, but there is no experience of the use 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 OR IMMUNOLOGICAL PROPERTIES

Phenylbutazone is a pyrazolone non-steroidal anti-inflammatory, analgesic and antipyretic agent**. ATC Vet Code:** QM01AA01

5.1 Pharmacodynamic properties

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.

Pharmacokinetic properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Sodium hydroxide
Water for injection

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

Store between +2 and +8°C.
Protect from light.

6.5 Nature and contents of immediate packaging

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

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

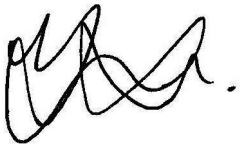
Vm 10434/4007

9. DATE OF FIRST AUTHORISATION

26 August 1994

10. DATE OF ANY REVISION OF THE TEXT

December 2022



Approved: 20 December 2022