SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Equipalazone 1 g Oral Paste

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	Per unit dose	% w/w
Phenylbutazone	1.00 g	16.66
Excipients		
Sodium Methyl Parahydroxybenzoate	0.006 g	0.10
Sodium Propyl Parahydroxybenzoate	0.0015 g	0.025

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 carpitis.

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 25ºC.
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 LAST RENEWAL OF THE AUTHORISATION

Date: 22 February 2006

10. DATE OF ANY REVISION OF THE TEXT

Date: November 2014

APPROVED T. NASH **13/11/14**