

PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 1 g oral paste

2. STATEMENT OF ACTIVE SUBSTANCES

Each unit dose (one marked division) contains 1 g phenylbutazone.

3. PACKAGE SIZE

36 g

4. TARGET SPECIES

Horses and ponies (non-food producing).



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period: 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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Replace cap after use.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

[Company logo]

14. MARKETING AUTHORISATION NUMBERS

Vm 50406/5035

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – SYRINGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 1 g oral paste

2. STATEMENT OF ACTIVE SUBSTANCES

Each unit dose (one marked division) contains 1 g phenylbutazone.

3. TARGET SPECIES

Horses and ponies (non-food producing).

4. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: 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.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
[Company logo]

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equipalazone 1 g oral paste

2. Composition

Each unit dose contains:

Active substance:

Phenylbutazone 1 g

Excipients:

Sodium methyl parahydroxybenzoate	0.006 g
Sodium propyl parahydroxybenzoate	0.0015 g

Off white paste prefilled into 32 ml syringes.

3. Target species

Horses and ponies (non-food producing).

4. Indications for use

The veterinary medicinal product is 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.

5. Contraindications

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

6. Special warnings

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.

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 gastrointestinal or vascular disorders, oral ulceration or inappetence 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.

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.

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.

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.

Overdose:

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.

Major incompatibilities:

None known.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.

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

Horses 450 kg (1000 lb) body weight:

2 unit doses twice on day one (equivalent to 8.8 mg/kg/day), 1 unit dose twice daily for four days (4.4 mg/kg/day) followed by 1 unit dose daily or on alternate days (2.2 mg/kg/day), sufficient to keep the animal comfortable.

Ponies 225 kg (500 lb) body weight:

1 unit dose (4.4 mg/kg) on alternate days.

Remove cap from nozzle, turn ring to required dosage and express as near to the back of the tongue as possible. Replace cap after use.

Adjust dose according to body weight.

Discontinue treatment if no response is evident after four to five days treatment.

9. Advice on correct administration

Avoid the introduction of contamination during use.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Replace cap after use.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50406/5035

Cardboard box with 1 x 32 ml dial-a-dose syringe (containing 6 unit doses).

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

Dechra Regulatory B.V.

Handelsweg 25

5531 AE Bladel

The Netherlands

[Company logo]

Manufacturer responsible for batch release:

Genera Inc.
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Kalinovica
10436 Rakov Potok
Croatia

Dales Pharmaceuticals
Snaygill Industrial Estate
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United Kingdom

Local representatives and contact details to report suspected adverse reactions:

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17. Other information

POM-V

Gavin Hall
Approved: 25 April 2025