LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 1 g oral powder for horses and ponies.
Phenylbutazone

2. STATEMENT OF ACTIVE SUBSTANCES

Each sachet contains: 1 g Phenylbutazone

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

32 sachets
100 sachets

5. TARGET SPECIES

Horses and ponies.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: 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.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Pregnant women or women attempting to conceive should avoid handling this product - read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in a dry place.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 10434/4090

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 1 g
Oral powder
For horses and ponies
Phenylbutazone

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each sachet contains: 1 g phenylbutazone.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1.5 g

4. ROUTE(S) OF ADMINISTRATION

For oral administration only.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period: 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.

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Equipalazone 1 g Oral powder for horses and ponies

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Manufacturer responsible for batch release:
Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 1 g oral powder for horses and ponies
Phenylbutazone

3. STATEMENT OF THE ACTIVE SUBSTANCEAND OTHER INGREDIENTS

Each sachet contains: 1 g phenylbutazone.
Oral powder. White/cream powder.

4. INDICATIONS

For 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, and in the reduction of post-surgical soft tissue reaction.

5. CONTRAINDICATIONS

Do not administer with other non-steroidal anti-inflammatory drugs (NSAIDs) 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 or where there is evidence of a blood dyscrasia.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

In common with other NSAIDs that inhibit prostaglandin synthesis, there may be gastric and/or renal intolerance. This is usually associated with overdosage and such events are rare. Recovery is usual on cessation of treatment and following the initiation of supportive symptomatic therapy.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

7. TARGET SPECIES

Horses and ponies (non-food producing).

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For oral administration only. When mixed with concentrate feed, the product was shown to be palatable to horses.
The dosage should be adjusted according to the individual animal's response, but the following may be taken as a guide:
Horses: 450 kg (1000 lb) body weight: Two sachets to be administered twice on day one (equivalent to 8.8 mg/kg/day) followed by one sachet twice daily for four days (4.4 mg/kg/day), then one sachet daily or on alternate days sufficient to keep the horse comfortable (2.2 mg/kg/day).
Ponies: 225 kg (500 lb) body weight: One sachet (4.4 mg/kg/day) on alternate days.
Discontinue treatment if no response is evident after four to five days treatment.

9. ADVICE ON CORRECT ADMINISTRATION

Administer the product mixed with a small quantity of feed.
Dampening of the veterinary medicinal product in feed 5 minutes prior to feeding has been shown to have no detrimental influence on the palatability of the product. However, the influence of prolonged dampening on palatability or stability of the product is not known.

10. WITHDRAWAL PERIOD

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.
Store in a dry place.
Do not use this veterinary medicinal product after the expiry date which is stated on the sachet and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species:
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 use in animals:
The therapeutic index of phenylbutazone is low. Do not exceed the stated dose or the duration of treatment.Use in any animal less than six weeks of age, or in aged animals, may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The product may cause hypersensitivity (allergic) reactions in those sensitised to phenylbutazone, either via skin contact or accidental inhalation.
People with known hypersensitivity to phenylbutazone, or any of the excipients, should avoid contact with this product.
If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes, or difficulty breathing, are more serious symptoms and require urgent medical attention.
This product can be irritating to the skin and eyes. Avoid contact with the eyes. In case of accidental eye contact, rinse eyes with plenty of water. If irritation persists seek medical advice. Wash any exposed skin and hands after use.
Care should be taken to avoid ingesting the powder. In the event of accidental ingestion, seek medical advice and show the product packaging to the physician.
The safety of phenylbutazone in pregnancy has not been established. The veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.
Use during pregnancy or lactation:
The safety of phenylbutazone in pregnancy and lactation has not been established. Use during pregnancy should be avoided whenever possible, particularly during the first trimester.
Use phenylbutazone in pregnant and lactating mares only according to a benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Some NSAIDs 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 potentially nephrotoxic drugs (e.g. aminoglycoside antibiotics) should be avoided.
Adverse reactions caused by phenylbutazone are exacerbated by concurrent administration of glucocorticoids, other non-steroidal antiphlogistics, or anticoagulants.
Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given NSAIDs.

Overdose (symptoms, emergency procedures, antidotes):
Overdosing may result in gastric and large intestinal ulceration and general enteropathy. Renal papillary damage may also occur with impaired renal function. Subcutaneous oedema, especially under the jaw may become evident due to plasma protein loss.
There is no specific antidote. If signs of possible overdosage occur, treat the animal symptomatically. 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.

Incompatibilities:
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

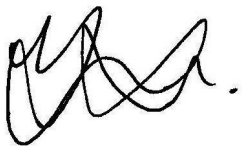
June 2022

15. OTHER INFORMATION

For animal treatment only.
To be supplied only on veterinary prescription.

Package quantities: Boxes of 32 and 100 sachets. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 05 October 2022