ANNEX III

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 paste
Phenylbutazone

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 unit dose (one marked division) contains:
Active substance:
Phenylbutazone 1 g
Excipients:
Sodium methyl parahydroxybenzoate 0.006 g
Sodium propyl parahydroxybenzoate 0.0015 g

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

36 g
One syringe of product contains six unit doses

5. TARGET SPECIES

Horses and ponies.

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

Oral.
Read the package leaflet before use.
Remove cap from nozzle. Turn ring to required dosage. Express the dose as near to the back of the tongue as possible. Replace cap after 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 WARNINGS

WARNING: Treated horses may never be slaughtered for human consumption

Read the package leaflet before use.Do not use in animals suffering from hepatic, cardiac or renal disease, gastric ulceration or blood dyscrasias.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Any contents remaining later than 28 days after the first opening should be discarded.

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

Disposal: Read package leaflet.

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

For animal treatment only.

To be supplied 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(S)

UK: Vm 10434/4006

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

UK: Vm 10434/4006 | POM-V | Prescription Only Medicine - Veterinarian

Once opened, use by: __/__/__

Prescribed dose:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 1 g
Oral paste
Phenylbutazone

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 unit dose (one marked division) contains:
Active substance:
Phenylbutazone 1 g
Excipients:
Sodium methyl parahydroxybenzoate 0.006 g
Sodium propyl parahydroxybenzoate 0.0015 g

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

36 g
One syringe of product contains six unit doses

4. ROUTE(S) OF ADMINISTRATION

Oral
Read the package leaflet before use.
Remove cap from nozzle. Turn ring to required dosage – each marked division (2 turns of the ring) is equivalent to 1 unit dose. Express the dose as near to the back of the tongue as possible. Replace cap after 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}
Once opened, used by:__/__/__

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

UK: Vm 10434/4006	POM-V	Prescription Only Medicine - Veterinarian

Do not use in animals suffering from hepatic, cardiac or renal disease, gastric ulceration or blood dyscrasias.
Target species: Horses and ponies.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Equipalazone 1 g
Oral paste

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

Dales Pharmaceuticals, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 1 g oral paste
Phenylbutazone

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 unit dose (one marked division) contains:
Active substance:
Phenylbutazone 1 g
Excipients:
Sodium methyl parahydroxybenzoate 0.006 g
Sodium propyl parahydroxybenzoate 0.0015 g
Palatable paste for oral administration.

4. INDICATIONS

Equipalazone 1 g oral paste 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 carpitis.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses and ponies.

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

For oral administration only.
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 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 25ºC.
Any contents remaining later than 28 days after the first opening should be discarded.
Replace cap after use.
Do not use after the expiry date which is stated on the label and carton after EXP.

12. SPECIAL WARNINGS

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.

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.

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.

Use during pregnancy and lactation:
The safety of phenylbutazone in pregnancy has not been established. 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.

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

03/2019

15. OTHER INFORMATION

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.

UK: Vm 10434/4006	POM-V	Prescription Only Medicine - Veterinarian

For animal treatment only.
To be supplied only on veterinary prescription.
Veterinary medicinal product authorised for use in UK and IE.

Package quantities:
Dial-a-dose syringes. One sysinge of product contains six unit doses. 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.
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom

Approved: 18 June 2019