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 200 mg/ml
Solution for injection
Phenylbutazone

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains**:** Phenylbutazone 200 mg
Excipients: Benzyl alcohol 0.015 ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Horses and ponies.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For administration by slow intravenous injection as a single dose, which may be followed if necessary by oral phenylbutazone therapy commencing 24 hours after the injection.
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

WARNING: Treated horses may never be slaughtered for human consumption

Do not use in animals suffering from hepatic, cardiac or renal disease, gastric ulceration or blood dyscrasias. There is a risk of irritancy if the injection is perivascular.
Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store between +2 and +8°C.
Protect from light.
Once the vial is broached, following withdrawal of the first dose use within 28 days.

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 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(S)

UK: Vm 10434/4007
IE: VPA 10799/003/001

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

POM-V

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IE: VPA 10799/003/001 | POM | Prescription Only Medicine

Once opened, use by: __/__/__

Prescribed dose:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 200 mg/ml
Solution for injection
Phenylbutazone

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains: Active substance: Phenylbutazone 200 mg
Excipient: Benzyl alcohol 0.015 ml

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Solution for injection
For administration by very slow intravenous injection as a single dose, which may be followed if necessary by oral phenylbutazone therapy commencing 24 hours after the injection.
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}
Once opened, used by:__/__/__

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

UK: Vm 10434/4007	POM-V	Prescription Only Medicine - Veterinarian

IE: VPA 10799/003/001	POM	Prescription Only Medicine

Target species: Horses and ponies.

Do not use in animals suffering from hepatic, cardiac or renal disease, gastric ulceration or blood dyscrasias. There is a risk of irritancy if the injection is previscular.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Equipalazone 200 mg/ml
Solution for injection

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipalazone 200 mg/ml solution for injection
Phenylbutazone

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml contains:
Active substance:
Phenylbutazone 200 mg
Excipients:
Benzyl alcohol 0.015 ml

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

4. INDICATIONS

Equipalazone 200 mg/ml solution for injection is indicated in 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).

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 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.
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, ROUTES AND METHOD OF ADMINISTRATION

Horses: 450 kg (1000 lb) body weight:
Maximum 10 ml (4.4 mg phenylbutazone/kg).
Ponies: 225 kg (500 lb) body weight:
Maximum 5 ml (4.4 mg phenylbutazone/kg).
Equipalazone 200 mg/ml solution for injection should be administered by slow intravenous injection as 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, the veterinary medicinal product may be administered once daily for not more than five consecutive days.

9. ADVICE ON CORRECT ADMINISTRATION

None.

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.
Protect from light.
Store between +2 and +8°C.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
Do not use this veterinary medicinal product after the expiry date 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 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.

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

Use during pregnancy and lactation:
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.

Interaction with other medicinal products and other forms of interaction:

Do not administer with other non-steroidal anti-inflammatory agents concurrently or within 24 hours of each other. 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.

Overdose (symptoms, emergency procedures, antidotes):
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

March2015

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 10434/4007	POM-V	Prescription Only Medicine - Veterinarian

IE: VPA 10799/003/001	POM	Prescription Only Medicine

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

Package quantities: 50 ml.

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: 21/07/2017