LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butagran Equi, 200 mg/g, oral powder for horses.
Phenylbutazone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Per g:
Phenylbutazone 200 mg

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

20 x 5 g
100 x 5 g

5. TARGET SPECIES

Horses.

6. INDICATIONS

The product is indicated for the treatment of musculo-skeletal conditions where relief from pain and a reduction in the associated inflammation is required e.g. in lameness associated with osteoarthritic conditions, bursitis, laminitis and soft tissue inflammation, particularly where continued mobility is considered desirable.

It is also of value in limiting post-surgical inflammation, myositis and other soft tissue inflammation.

The product can be used as an anti-pyretic where this is considered advisable e.g. in viral respiratory infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Not 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, the sachet should be used immediately.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep sachets in outer carton.

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

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

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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 28365/4004

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butagran Equi, 200 mg/g, oral powder for horses.
Phenylbutazone

2. QUANTITY OF THE ACTIVE SUBSTANCE

Phenylbutazone 200 mg/g

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

5 grams

4. ROUTE(S) OF ADMINISTRATION

For oral administration.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Not for use in horses intended for human consumption

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
Butagran Equi, 200 mg/g, oral powder for horses

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

Marketing authorisation holder:
Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

Manufacturer for the batch release:
Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butagran Equi, 200 mg/g, oral powder for horses.
Phenylbutazone

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Per g:
Active substance:
Phenylbutazone 200 mg

White powder

4. INDICATIONS

The product is indicated for the treatment of musculo-skeletal conditions where relief from pain and a reduction in the associated inflammation is required e.g. in lameness associated with osteoarthritic conditions, bursitis, laminitis and soft tissue inflammation, particularly where continued mobility is considered desirable.

It is also of value in limiting post-surgical inflammation, myositis and other soft tissue inflammation.

The product can be used as an anti-pyretic where this is considered advisable e.g. in viral respiratory infections.

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance, or to any of the excipients.
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.

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 (more than 1 but less than 10 animals in 10,000 animals treated). Recovery is usual on cessation of treatment and following the initiation of supportive symptomatic therapy (see special warnings - overdose for further information).
Blood dyscrasia may occur.
Ponies are very sensitive to gastric ulceration with this product, even at therapeutic doses (diarrhoea, ulceration in the mouth and hypoproteinaemia may also be seen).
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
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 inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

For oral administration.

For each 450 kg of body weight the following dosage guide should be used according to individual response:

Day 1: Two sachets or 10 g of product twice daily (equivalent to 4.4 mg of phenylbutazone/kg of BW on each occasion).

Day 2-4: One sachet or 5 g of product twice daily (equivalent to 2.2 mg of phenylbutazone/kg of BW on each occasion) followed by one sachet or 5 g daily (2.2 mg of phenylbutazone/kg of BW daily) or on alternate days as required.

9. ADVICE ON CORRECT ADMINISTRATION

If no response is evident after 4-5 days, discontinue treatment. Hay may delay the absorption of phenylbutazone and so the onset of a clinical effect. It is advisable not to administer hay immediately prior to, or during the administration of the product.

For ease of administration the product may be mixed with a limited quantity of bran or oats.

10. WITHDRAWAL PERIOD

Not 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.
Keep sachets in outer carton. Do not use after the expiry date stated on the sachet after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the sachet: use immediately after opening.

12. SPECIAL WARNINGS

Special warnings for each target species
The clinical effects of phenylbutazone can be evident for at least three days following cessation of therapy. This should be borne in mind when examining horses for soundness.

Special precautions for use in animals
Do not exceed the stated dose as the therapeutic index of phenylbutazone is low.
Use in any animal less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided, animals may require careful clinical management.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal as there is a potential risk of increased renal toxicity. Keep water readily available during the treatment period to avoid dehydration.
NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product may cause hypersensitivity (allergic) reaction in those sensitised to phenylbutazone, either via skin contact or accidental ingestion.
People with known hypersensitivity to phenylbutazone should avoid contact with this product.
If you develop symptoms following exposure, such as a 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 the eyes. Avoid contact with the eyes. In case of accidental eye contact, irrigate eyes with plenty of clean water. If irritation persists, seek medical advice.
Care should be taken to avoid inhaling or ingesting the powder. In the event of accidental inhalation or ingestion, seek medical advice and show the product packaging to the doctor.
Wash any exposed skin and hands after use.

<u>Pregnancy:</u>

Care should be exercised if administered to pregnant mares. Although no adverse effects of phenylbutazone on the foetus or maintenance of pregnancy have been reported during field use, no definitive safety studies have been carried out in the mare.
Foetotoxic effects of phenylbutazone have been recorded in experimental animal species at high dose levels.
Lactation:
The safety of the product in lactating mares has not been demonstrated. If the administration of phenylbutazone to pregnant or lactating mares is considered essential the potential benefits should be weighed against the potential hazard to the mare and/or foal.
Avoid use around time of parturition.

Interaction with other medicinal products and other forms of interaction
Concurrent administration of potential nephrotoxic drugs should be avoided.
Phenylbutazone is extensively bound to plasma proteins. It may displace other drugs that are highly protein-bound e.g. some sulphonamides, warfarin or it may itself be displaced to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.
Concurrent therapy with other therapeutic agents should be undertaken with caution due to the risk of metabolic interactions. Phenylbutazone may interfere with the metabolism of other drugs e.g. warfarin, barbiturates, with resultant toxicity.
There is evidence to indicate that the pharmacokinetics of penicillin and gentamicin products may be affected by concurrent administration of products containing phenylbutazone with a possible reduction of therapeutic efficacy, since tissue penetration may be reduced. The distribution of other drugs given concurrently may also be affected.
Do not administer other NSAIDs concurrently or within 24 hours of each other.
Phenylbutazone induces hepatic microsomal enzyme activity.

Overdose (symptoms, emergency procedures, antidotes), if necessary
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.

Incompatibilities
Do not mix this product with any other veterinary medicinal product.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
Boxes of 20 or 100 sachets

Not all pack sizes may be marketed.

Approved: 11 January 2018