PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for sachets (100s)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazone 1 g, oral powder for horses.
Phenylbutazone

2. STATEMENT OF ACTIVE SUBSTANCES

Each sachet of 5 g contains 1g of Phenylbutazone

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

100 x 5 g sachets

5. TARGET SPECIES

Horses (non-food producing horses).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

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

Day 1 4.4 mg phenylbutazone/kg of bodyweight twice daily, (equivalent to two sachets or 10 g of the product twice daily).
Day 2-4 2.2 mg phenylbutazone /kg of bodyweight twice daily, (equivalent to one sachet or 5 g of the product twice daily) followed by 2.2 mg phenylbutazone /kg of bodyweight daily, (equivalent to one sachet or 5 g of the product daily) or on alternate days as required.

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 quantity of bran or oats before each treatment.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

This product may cause hypersensitivity (allergic) reactions in those sensitized 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 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 inhaling or ingestion, seek medical advice and show the product packaging to the physician. Wash any exposed skin and hands after use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material 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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/4066

17. MANUFACTURER'S BATCH NUMBER

BN{number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for sachets (16s)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazone 1 g, oral powder for horses.
Phenylbutazone

2. STATEMENT OF ACTIVE SUBSTANCES

Each sachet of 5 g contains 1g of Phenylbutazone

3. PHARMACEUTICAL FORM

Oral powder

4. PACKAGE SIZE

16 x 5 g sachets

5. TARGET SPECIES

Horses (non-food producing horses).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material 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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/4066

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazone 1 g, oral powder for horses.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Phenylbutazone 1g/sachet

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

5 g.

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

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

BN {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET:
Chanazone 1 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 and manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazone 1 g, oral powder for horses.
Phenylbutazone

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

Each sachet of 5 g contains: 1g of Phenylbutazone,
Off white to yellow powder.

4. INDICATION(S)

The product is indicated for the treatment of musculoskeletal conditions in the horse 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.
Phenylbutazone powder can be used as an anti-pyretic where this is considered advisable e.g. in viral respiratory infections.

5. CONTRAINDICATIONS

Do not use in animals with known 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 gastro-intestinal ulceration or bleeding or where there is evidence of a blood dyscrasia.
Do not use in animals suffering from thyroid disease.
Do not use in animals with severe hypertonia.

Do not use in animals with lesions in the intestinal mucosa, caused by parasitic infestations.

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
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 (non-food producing horses).

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

Oral use.
The recommended dose rate is 4.4 – 8.8 mg/kg per day.

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

Day 1 4.4 mg phenylbutazone/kg of bodyweight twice daily, (equivalent to two sachets or 10 g of the product twice daily).
Day 2-4 2.2 mg phenylbutazone /kg of bodyweight twice daily, (equivalent to one sachet or 5 g of the product twice daily) followed by 2.2 mg phenylbutazone /kg of bodyweight daily, (equivalent to one sachet or 5 g of the product daily) or on alternate days as required.

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 quantity of bran or oats before each treatment.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

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.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date (EXP) stated on the carton and the sachet.
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.
The International Federation for Equestrian Sports (FEI) regards phenylbutazone as prohibited substance in the context of a participation of the treated horse in equestrian sport events. A horse, which is or has recently been under treatment with the product, might not be allowed to participate in sport events. Please refer to recommendations of the FEI, national laws and national association rules for withdrawal times prior to competition.

Special precautions for use in animals:
Do not exceed the stated dose of 8.8 mg/kg/day 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 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.

NSAID's can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be considered.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may cause hypersensitivity (allergic) reactions in those sensitized 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 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 inhaling or ingestion, seek medical advice and show the product packaging to the physician.
Wash any exposed skin and hands after use.

Pregnancy and lactation:
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.

Use phenylbutazone in pregnant and lactating mares only according to a benefit/risk assessment by the responsible veterinarian. Avoid use around time of parturition.

Interaction with other medicinal products and other forms of interaction:
Do not administer other NSAID's concurrently or within 24 hours of each other.
Concurrent administration of potential nephrotoxic drugs should be avoided.
Phenylbutazone induces hepatic microsomal enzyme activity.
There is a potential risk of increased renal toxicity after concurrent administration of aminoglycosides.
Concomitant use of glucocorticoids, other NSAIDs or anticoagulants increase adverse effects of phenylbutazone.
Therapeutic efficacy of diuretics may be reduced when used in combination with phenylbutazone-containing products

Phenylbutazone is extensively bound to plasma proteins. It may displace other drugs that are highly protein bound, e.g. some sulphonomides, 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 in other drugs given concurrently may also be affected.

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.
In case of overdose CNS effects (excitement, seizures), hematuria and acidosis were observed. 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

December 2020

15. OTHER INFORMATION

To be supplied only on veterinary prescription.
Pack size: 5 g sachets available in packs of 16 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 12 February 2021