SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazone 1 g, oral powder for horses.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of 5 g contains:

Active substance:
Phenylbutazone 1 g

Excipients:

Qualitative composition of excipients and other constituents
Glucose Monohydrate
Povidone
Apple Flavour
Xanthan Gum
Crospovidone

Off white to yellowish coloured granular powder

3. CLINICAL INFORMATION

3.1 Target species

Horses (non-food producing horses).

3.2 Indications for use for each target species

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.
Alleviation of post surgical inflammation, myositis and other soft tissue inflammation.
The veterinary medicinal product can be used as an anti-pyretic where this is considered advisable e.g. in viral respiratory infections.

3.3 Contraindications

Do not use in 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 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.
NSAIDs 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 case of accidental inhaling or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash any exposed skin and hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Digestive tract disorder [1,2] Renal disorder [1]
Undetermined frequency (cannot be estimated from the available data)	Blood dyscrasia

[1] In common with other NSAIDs that inhibit prostaglandin synthesis there may be gastric and/or renal intolerance. This is usually associated with overdosage. Recovery is usual on cessation of treatment and following the initiation of supportive symptomatic therapy (see section 3.10 for further information).
[2] Ponies are very sensitive to gastric ulceration with this veterinary medicinal 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.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer other NSAIDs 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.

3.9 Administration routes and dosage

Oral use.
The recommended dose rate is 4.4 – 8.8 mg/kg bodyweight per day.
The dosage should be adjusted according to the individual animal's response, but the following may be taken as a guide:
Horse (450 kg bodyweight):
Day 1: 4.4 mg phenylbutazone/kg bodyweight twice daily, (equivalent to two sachets or 10 g of the veterinary medicinal product twice daily).
Day 2-4: 2.2 mg phenylbutazone /kg bodyweight twice daily, (equivalent to one sachet or 5 g of the veterinary medicinal product twice daily) followed by 2.2 mg phenylbutazone /kg bodyweight daily, (equivalent to one sachet or 5 g of the veterinary medicinal product daily) or on alternate days as required.
If no response is evident after 4-5 days, discontinue treatment. Hay intake 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 veterinary medicinal product.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AA01.

4.2 Pharmacodynamics

Phenylbutazone is a pyrazolone non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and antipyretic activity. These pharmacodynamic effects are achieved by the nonselective inhibition of prostaglandin synthetases (cyclooxygenases COX-1 and COX-2).

4.3 Pharmacokinetics

The plasma elimination half-life of phenylbutazone in the horse varies from 3.5 to 8.0 hours. Normally peak plasma levels are achieved approximately 2-3 hours after administration.

Oral bioavailability is high but absorption may be delayed if administered on a full stomach. Due to binding, hay in the diet may further delay absorption and so the onset of a clinical effect.
Phenylbutazone binds heavily to plasma albumin.
Phenylbutazone is metabolised in the liver to oxphenbutazone, which also has similar pharmacological activity.
Further metabolism takes place to gamma-hydroxyphenylbutazone. Excretion is mainly via the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Paper foil sachets (Paper/LDPE/Foil/LDPE) containing 5g of powder per sachet.
Pack sizes: 16 sachets and 100 sachets in a cardboard box.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 08749/4066

8. DATE OF FIRST AUTHORISATION

15 March 2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

March 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 12 May 2025
Gavin Hall