# 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.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral powder
An off white to yellowish coloured granular powder

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Horses (non-food producing horses).

### 4.2 Indications for use, specifying the target species

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.

### 4.3 Contraindications

Do not use in cases of 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.

## 4.4 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.

## 4.5 Special precautions for use

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.
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 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.

**4.6 Adverse reactions (frequency and seriousness)**

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 4.10 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.

**4.7 Use during pregnancy, lactation or lay**

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.

**4.8 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.

## 4.9 Amounts to be administered and administration route

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.

## 4.10 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.
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.

## 4.11 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.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and Anti-rheumatic products, non-steroids
ATCvet code: QM01AAO1.

### 5.1 Pharmacodynamic properties

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).

### 5.2 Pharmacokinetic particulars

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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Glucose Monohydrate
Povidone
Apple Flavour
Xanthan Gum
Crospovidone

### 6.2 Major incompatibilities

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

### 6.3 Shelf life

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

### 6.4 Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

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

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

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

## 7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

## 8. MARKETING AUTHORISATION NUMBER

Vm 08749/4066

## 9. DATE OF FIRST AUTHORISATION

15 March 2016

## 10. DATE OF REVISION OF THE TEXT

February 2021

Approved 12 February 2021