SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butagran Equi 200 mg/g oral powder for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Phenylbutazone 200 mg

Excipients:

Qualitative composition of excipients and other constituents
Glucose Monohydrate
Hypromellose
Butter vanilla flavour

White powder.

3. CLINICAL INFORMATION

3.1 Target species

Horses (non-food producing).

3.2 Indications for use for each target species

The veterinary medical 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 veterinary medical 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 gastrointestinal ulceration or bleeding or where there is evidence of a blood dyscrasia.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

Non-steroidal anti-inflammatory drugs (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 veterinary medicinal 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 the veterinary medicinal 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 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 inhalation 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):	Gastric irritation[1] Renal disorder[1]
Undetermined frequency (cannot be estimated from the available data):	Blood dyscrasia Gastric ulceration[2] Diarrhoea[2] Oral ulceration[2] Hypoproteinaemia[2]

[1] Usually associated with overdosage. Recovery is usual on cessation of treatment and following the initiation of supportive symptomatic therapy. See section 3.10.

[2] Ponies are very sensitive, even at therapeutic doses.

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 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

Pregnancy:
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. If the administration of phenylbutazone to pregnant 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.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation.
If the administration of phenylbutazone to lactating mares is considered essential the potential benefits should be weighed against the potential hazard to the mare and/or foal.

3.8 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.

3.9 Administration routes and dosage

Oral use.

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 veterinary medicinal 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 veterinary medicinal product twice daily (equivalent to 2.2 mg of phenylbutazone/kg of BW on each occasion) followed by one sachet or 5 g of veterinary medicinal product daily (2.2 mg of phenylbutazone/kg of BW 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 veterinary medicinal product.

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

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.

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 for use in horses intended for human consumption. Not for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AA01

4.2 Pharmacodynamics

Phenylbutazone is a pyrazolone NSAID with analgesic, anti-inflammatory and anti-pyretic activity. These pharmacodynamic effects are achieved by the inhibition of prostaglandin synthetase (cyclo-oxygenase).

4.3 Pharmacokinetics

The plasma elimination half-life of phenylbutazone in the horse varies from 3.5 - 8.0 hours. Normally peak plasma levels are achieved approximately 2-3 hours after administration. Oral bioavailability is high but concurrent feeding of hay can delay the time to peak concentration, decreases the peak plasma concentrations and so delay the onset of a clinical effect.

Phenylbutazone binds heavily to plasma albumin.

Phenylbutazone is metabolised in the liver to oxyphenbutazone, 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.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

- Heat-sealed PET/LDPE/aluminium foil/LDPE laminated sachet of 5 grams of veterinary medicinal product;
- Heat-sealed aluminium foil/LDPE/paper/LDPE laminated sachet of 5 grams of veterinary medicinal product.
- Sachets are packed in a cardboard box containing 20 or 100 sachets for single use.

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

Dopharma Research B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 28365/4004

8. DATE OF FIRST AUTHORISATION

08 February 2013

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

September 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.

Gavin Hall
Approved: 08 December 2025