# BUTAGRAN EQUI®

**200 mg/g, Oral powder for horses**
**Flavoured Phenylbutazone Sachet**

# DATA SHEET

## 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.

## BENEFITS

- **For treatment of musculoskeletal injuries**
- **For pain relief**
- **For soft tissue injuries**
- **For reducing inflammation**
- **With butter vanilla flavour**


| LIST No | UNIT PACKAGE |
|---|---|
| 1BUT001 | 100 x 5gr sachets |

**See reverse for Administration & Dosage**

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## Flavoured Phenylbutazone Sachet

### PRESENTATION
Oral white powder containing 200mg/g phenylbutazone in a 5 g sachet.

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

### CONTRA-INDICATIONS & WARNINGS
Do not use in animals with known hypersensitivity to the active ingredient.
Use is contra-indicated 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.

### 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.
FEI regards phenylbutazone as a prohibited substance, it should not be administered at least 8 days before the competition.

### SPECIAL PRECAUTIONS FOR USE
**i. 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.
**ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals**
• Wash hands after use
• 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.
**iii. 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. Recovery is usual on cessation of treatment and following the initiation of supportive symptomatic therapy
• 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)

### 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.
**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.

### OVERDOSING
• 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.

### WITHDRAWAL PERIODS
• 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.

### PHARMACEUTICAL INFORMATION
**Pharmacodynamic properties**
Phenylbutazone is a pyrazolone non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and anti-pyretic activity. These pharmacodynamic effects are achieved by the inhibition of prostaglandin synthetase (cyclo-oxygenase).
**Pharmacokinetic properties**
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, decrease 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.

### PHARMACEUTICAL PARTICULARS
**List of excipients**
Glucose Monohydrate
Methylhydroxypropylcellulose,(Hypromellose)
Butter vanilla flavour

### INCOMPATABILITIES
Do not mix this product with any other veterinary medicinal product.
**Storage and disposal**
Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately after opening.
Do not store above 25°C.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

### LEGAL CATEGORY
POM-V

### MARKETING AUTHORISATION HOLDER
**Dopharma Research B.V.**
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The Netherlands
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### MARKETED IN UK BY
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### MARKETING AUTHORISATION NUMBER
**VM 28365/4004**

TAKE TIME OBSERVE LABEL DIRECTIONS

www.bimeda.co.uk

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