

PARTICULARS TO APPEAR ON THE OUTER PACKAGE – CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butaleve 1 g oral powder

2. STATEMENT OF ACTIVE SUBSTANCES

Each sachet contains 1 g phenylbutazone

3. PACKAGE SIZE

32 sachets

100 sachets

4. TARGET SPECIES

Horses and ponies (non-food producing).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period: Not authorised 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.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Store in a dry place.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder: Dechra Regulatory B.V.

Distributed by: CVS UK Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 50406/5048 (GB)

Vm 50406/3042 (NI)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS - SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butaleve 1 g oral powder



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each sachet contains 1 g phenylbutazone.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Butaleve 1 g oral powder for horses and ponies

2. Composition

Each sachet contains:

Active substance:

Phenylbutazone 1 g

White/cream powder.

3. Target species

Horses and ponies (non-food producing).

4. Indications for use

For the treatment of musculoskeletal disorders in horses and ponies where the anti-inflammatory and analgesic properties of phenylbutazone can offer relief, for example, in lameness associated with osteoarthritic conditions, acute and chronic laminitis, bursitis and carpalis, and in the reduction of post-surgical soft tissue reaction.

5. Contraindications

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

Do not administer with other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

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.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

The clinical effect of phenylbutazone can be evident for at least three days following cessation of administration. This should be borne in mind when examining horses for soundness.

Special precautions for safe use in the target species:

Use in any animal less than six weeks of age, or in aged animals, may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal as there is a risk of increased toxicity.

It is preferable that NSAIDs which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.

Response to long-term therapy should be monitored at regular intervals by a veterinary practitioner.

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:

The veterinary medicinal product should be handled with care at all times to reduce the risk of accidental ingestion, skin contact or dust inhalation. If accidental skin or eye contact occurs, the site should be washed immediately with water. If the product is ingested, seek medical advice immediately and show the product packaging.

Advice to doctors: gastric lavage (emesis in children) should be performed urgently. Charcoal haemoperfusion has also been shown to be beneficial. Treatment should then be administered symptomatically.

Pregnancy:

The safety of the veterinary medicinal product in pregnancy has not been established.

Use during pregnancy should be avoided whenever possible, particularly during the first trimester.

Interaction with other medicinal products and other forms of interaction:

Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.

Concurrent administration of potentially nephrotoxic drugs (e.g. aminoglycoside antibiotics) should be avoided.

Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given NSAIDs.

Overdose:

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. The therapeutic index of phenylbutazone is low. In man, charcoal haemoperfusion in conjunction with dopamine has been used successfully to treat overdosage with phenylbutazone, but there is no experience of the use of this technique in the horse.

Major incompatibilities:

None known.

7. Adverse events

Horses and ponies (non-food producing):

Rare (1 to 10 animals / 10,000 animals treated):	Gastric intolerance* Renal disorder*
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* 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.

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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.

When mixed with concentrate feed, the veterinary medicinal product was shown to be palatable to horses.

The dosage should be adjusted according to the individual animal's response, but the following may be taken as a guide:

Horses 450 kg (1000 lb) body weight: Two sachets to be administered twice on day one (equivalent to 8.8 mg/kg/day) followed by one sachet twice daily for four days (4.4 mg/kg/day), then one sachet daily or on alternate days sufficient to keep the horse comfortable (2.2 mg/kg/day).

Ponies 225 kg (500 lb) body weight: One sachet (4.4 mg/kg/day) on alternate days. Discontinue treatment if no response is evident after four to five days treatment.

9. Advice on correct administration

For ease of administration mix the powder with a small quantity of feed. Dampening of the veterinary medicinal product in feed 5 minutes prior to feeding has been shown to have no detrimental influence on the palatability of the veterinary medicinal product. However, the influence of prolonged dampening on palatability or stability of the veterinary medicinal product is not known.

10. Withdrawal periods

Not authorised 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.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
Store in a dry place.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50406/5048 (GB)

Vm 50406/3042 (NI)

Cardboard box containing 32 or 100 sachets.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

Dechra Regulatory B.V.

Handelsweg 25

5531 AE Bladel

The Netherlands

Manufacturer responsible for batch release:

Dales Pharmaceuticals Limited

Snaygill Industrial Estate

Keighley Road

Skipton

North Yorkshire

BD23 2RW

United Kingdom

Genera d.d.

Svetonedeljska cesta 2

Kalinovica

10436 Rakov Potok

Croatia

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved: 23 September 2025