

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Butazocare flavour 1g granules in sachet for horses and ponies

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**Each 2 g sachet contains:**

**Active substance:**

Phenylbutazone (microencapsulated) 1 g

**Excipients:**

| <b>Qualitative composition of excipients and other constituents</b> |
|---------------------------------------------------------------------|
| Cellulose microcrystalline                                          |
| Ethylcellulose                                                      |
| Hypromellose                                                        |
| Magnesium stearate                                                  |
| Sucrose                                                             |
| Peppermint flavour                                                  |

White to off-white granules.

### **3. CLINICAL INFORMATION**

#### **3.1 Target species**

Horses (non-food producing), ponies (non-food producing)

#### **3.2 Indications for use for each target species**

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

#### **3.3 Contraindications**

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 animals suffering from gastrointestinal diseases. Do not use in animals with haemorrhagic diathesis.

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

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

### **3.4 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.

### **3.5 Special precautions for use**

Special precautions for safe use in the target species:

Use in any animal under six weeks of age, or in aged animals, may involve additional risks. If such use cannot be avoided, animals may require a reduced dosage and special 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.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product may cause hypersensitivity (allergic) reactions in those sensitised to phenylbutazone, either via skin contact or accidental inhalation.

People with known hypersensitivity to phenylbutazone, should avoid contact with this veterinary medicinal product.

If you develop symptoms following exposure, such as skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. 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 immediately and show the

package leaflet or the label to the physician. Wash any exposed skin and hands after use.

Care should be taken to avoid ingesting the powder. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Horses (non-food producing), ponies (non-food producing):

|                                                                     |                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rare<br>(1 to 10 animals / 10,000 animals treated):                 | Digestive tract disorders <sup>1</sup><br>Renal disorder <sup>1</sup>                                                                                                                                                                                                                         |
| Undetermined frequency<br>(cannot be estimated from available data) | Inappetence<br>Apathy<br>Colic, weight loss, diarrhoea<br>Occult gastrointestinal bleeding<br>Hypoproteinemia <sup>2</sup><br>Oedema <sup>3</sup><br>Leucopenia<br>Blood and lymphatic system disorder <sup>4</sup><br>Anaemia, thrombocytopenia<br>Elevated aspartate aminotransferase (AST) |

<sup>1</sup>Gastric and/or renal intolerance, 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).

<sup>2</sup>Due to intestinal protein loss.

<sup>3</sup>Hematopoietic dysfunction. Due to sodium and potassium loss.

<sup>4</sup>Due to hematopoietic dysfunction.

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 and lactation:

Phenylbutazone crosses the placenta and passes into milk in lactating animals. Use during pregnancy should be avoided whenever possible, particularly during the first trimester.

### 3.8 Interaction with other medicinal products and other forms of interaction

Phenylbutazone may be highly bound to plasma proteins and compete with other highly bound drugs (e.g. sulphonamides) to produce an increase in non-bound pharmacologically active concentrations which can lead to toxic effects.

Phenylbutazone induces enzymatic activity and thus affect plasma levels and efficacy of other drugs.

Due to inhibition of renal prostaglandin synthesis, efficacy of diuretics is reduced. Elimination of penicillin is reduced.

Adverse reactions caused by phenylbutazone are exacerbated by concurrent administration of glucocorticoids, other non-steroidal antiphlogistics, or anticoagulants.

### 3.9 Administration routes and dosage

Oral use.

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: the contents of two sachets to be administered twice on day 1 of treatment (equivalent to 8.8 mg/kg/day) followed by the contents of 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) on alternate days.

Discontinue treatment if no response is evident after four to five days treatment.

For ease of administration mix the powder with a small quantity of feed.

### 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.

Acute overdosing may result in central nervous symptoms (seizures, excitations), haematuria acidosis. If signs of overdose are observed treatment with phenylbutazone is to be discontinued.

The therapeutic index of phenylbutazone is low.

### **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 authorized 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.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code : QM01AA01**

### **4.2 Pharmacodynamics**

Phenylbutazone acts by inhibiting the production of prostaglandins. Prostaglandins possess a wide variety of physiological properties, including those involved in the production of pain, inflammation and pyrexia. The main metabolite, oxyphenbutazone, possesses similar pharmacological properties.

### **4.3 Pharmacokinetics**

Phenylbutazone is generally well absorbed following oral administration. The rate, but not the extent, of absorption may be affected due to binding of phenylbutazone to food and the contents of the gastrointestinal tract.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

None known.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

### **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**

Sachets of a paper/polyethylene outer layer and aluminium/polyethylene inner layer in packs of 32 and 100 sachets. Each sachet contains 2 g Butazocare powder. The sachets are packaged in a carton.

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**

Ecuphar NV

#### **7. MARKETING AUTHORISATION NUMBER**

Vm 32742/4026

#### **8. DATE OF FIRST AUTHORISATION**

16 April 2019

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

July 2026

#### **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](http://www.gov.uk).

*Gavin Hall*

Approved: 11 August 2026