ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butazocare flavour 1g granules in sachet for horses and ponies
Phenylbutazone

2. STATEMENT OF ACTIVE SUBSTANCES

Each sachet contains 1 g phenylbutazone (microencapsulated)

3. PHARMACEUTICAL FORM

White to off-white granules in sachet for oral administration.

4. PACKAGE SIZE

32 Sachets
100 Sachets

5. TARGET SPECIES

Horses and ponies (non-food producing).

6. INDICATION(S)

For the treatment of musculoskeletal disorders in horses and ponies. (Read package leaflet for full indications.)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

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 twice daily on day 1 of treatment (equivalent to 8.8 mg/kg/day) followed 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.

8. 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>
Once opened, use sachet immediately.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 32742/4026

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{SACHET}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butazocare flavour 1g granules in sachet for horses and ponies
Phenylbutazone

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Phenylbutazone (microencapsulated) 1g/sachet

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2g

4. ROUTE(S) OF ADMINISTRATION

Oral administration

5. 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.

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Butazocare flavour 1g granules in sachet for horses and ponies

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:

Laboratoria Smeets N.V.
Fotografielaan 42
B-2610 Antwerpen-Wilrijk
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butazocare flavour 1g granules in sachet for horses and ponies
Phenylbutazone

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:
Each sachet contains 1 g phenylbutazone (microencapsulated)

White to off-white granules in sachet for oral administration.

4. INDICATION(S)

For the treatment of musculoskeletal disorders in horses and ponies 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 carpitis, and in the reduction of post-surgical soft tissue reaction.

5. 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 known hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

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 (see 4.10 for further information).
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

- inappetence
- apathy
- colic
- weight loss
- diarrhoea
- gastrointestinal bleeding
- intestinal protein loss which can result in hypoproteinemia
- sodium and potassium loss which can result in oedema
- thrombocytopenia
- leucopenia
- hematopoietic dysfunction
- anemia
- increased aminotransferase levels

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Horses and ponies (non-food producing).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

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

Once opened, use sachet immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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 use in animals:

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:

- This 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 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. Wash any exposed skin and hands after use.
- Care should be taken to avoid ingesting the powder. In the event of accidental ingestion, seek medical advice and show the product packaging to the physician.

Pregnancy, lactation or lay

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

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. sulfonamides) 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 are reduced.
Elimination of penicillin is reduced.
Adverse reactions caused by phenylbutazone are exacerbated by concurrent administration of glucocorticoids, other non-steroidal antiphlogistics, or anticoagulants.
Do not administer with other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.
Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given NSAIDs.

Overdose (symptoms, emergency procedures, 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. 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.

There is no specific antidote. If signs of possible overdosage occur, treat the animal symptomatically.
The therapeutic index of phenylbutazone is low.

Incompatibilities:

None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

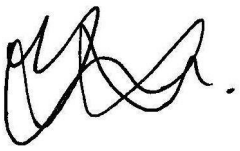
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

Pack sizes of 32 or 100 sachets. Each sachet contains 2 g Butazocare powder.
Not all pack sizes may be marketed.
To be supplied only on veterinary prescription.



Approved: 11 August 2022