[Version 1 05/02/18]

ANNEX I

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

Active substance:	per sachet
Phenylbutazone (microencapsulated)	1g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Horses and ponies (non-food producing).

4.2 Indications for use, specifying the target species

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.

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

4.4 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.

4.5 Special precautions for use

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.

4.6 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 (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).

4.7 Use during 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.

4.8 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. 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.

4.9 Amounts to be administered and administration route

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.

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids.

ATC vet code: QM01AA01

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose microcrystalline
Ethylcellulose
Hypromellose
Magnesium stearate
Sucrose
Peppermint flavour

6.2 Major incompatibilities

None known.

6.3 Shelf life

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

6.4. Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgien

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT