SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Phenylbutazone 200mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance(s) mg/tablet

Phenylbutazone.....……200

Excipients

Titanium Dioxide (E171)……...0.85

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Tablet
White, sugar coated.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Indicated in dogs of 20kg and over for the treatment of osteoarthritis, acute musculo-skeletal trauma, spondylitis, bursitis and inflammation of ligament, rheumatoid and other arthritic diseases.

4.2 Contra-indications

Phenylbutazone 200mg should not be administered to dogs weighing less than 20kg bodyweight.
Do not exceed the stated dose or duration of the treatment.
Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastrointestinal ulceration or bleeding, where there is evidence of blood dyscrasia or hypersensitivity to the product.
Do not administer other NSAID's concurrently or within 24 hours of each other.
Not to be used in cats.

4.4 Special Warnings for each target species

Some NSAID's 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.
Use in animals less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided animals may require a reduced dosage ad careful clinical management.
Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increase renal toxicity.
Concurrent administration of potentially nephrotoxic drugs should be avoided.

4.5 Special precautions for use

i. Special precautions for use in animals

In suspected case of renal or hepatic dysfunction an EDTA and clotted blood sample should be taken in order that relevant haematological and biochemical assays can be carried out prior to commencement of treatment.
Treatment should be discontinued in animals developing gastro-intestinal symptoms or vascular disorders.
NSAID's 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 medicinal product to animals

Phenylbutazone can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If the product is accidentally ingested, seek medical advice immediately and show the product packaging to the doctor. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In the dog, gastro-intestinal toxicity is rare and confined to sporadic individual case reports with recovery following withdrawal of the drug ± medication with cimetidine, antacids and fluid therapy.
In the dog myelotoxic reactions are exceptional with very few cases reported in scientific journals, in spite of the widespread use of phenylbutazone in dogs.
These reactions in the dog are also considered to be unpredictable and the result of individual sensitivity, independent of dose. However the adverse effects on canine blood and cardiovascular systems have generally been shown to be reversible following phenylbutazone withdrawal ± appropriate therapies.
Nephropathy and hepatoxicity have been rarely reported in the dog.

4.7 Use during Pregnancy, lactation or lay

Although there have been occasional reports of teratogenic effects of NSAID's in humans, there have been no reports following the use of phenylbutazone in dogs.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer other NSAID's concurrently or within 24 hours of each other. NSAID's can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.
It is preferable that NSAID's which inhibit prostaglandin synthesis are not administered to animals undergoing anaesthesia until fully recovered.

4.9 Amounts to be administered and administration route

For oral administration only.
20mg/kg daily for 7 days preferably in divided doses every 8 or 12 hours, followed by 10mg/kg daily for 7 days preferably in divided doses every 8-12 hours.
Phenylbutazone 200mg should not be administered to dogs weighing less than 20kg bodyweight.
The tablets should be administered whole, with or immediately after food. In older dogs suffering chronic musculo-skeletal disease the course of treatment as the lower dose may be extended but the patient must be regularly monitored for any possible adverse effects.
In cases of trauma, if symptoms persist after the initial two week course of treatment, the diagnosis should be reassessed.

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

Acute overdose:
Typical symptoms include lethargy, elevated pulse rate, respiratory rate and elevated temperature.
In cases of known acute overdose where immediate attention is available, induce vomiting. Otherwise attempt to reduce absorption from the gastro-intestinal tract by administration of a suitable (such as charcoal/kaolin based) adsorbent.
There is no known specific antidote.
The half life of phenylbutazone is short so clinical improvement should be apparent within 24 to 48 hours after acute overdose.

Chronic overdose:
Typical symptoms include elevated pulse rare and temperature depression, weakness, lethargy and anorexia.
No specific antidote is available.
Many disorders associated with chronic overdose are reversible. Cessation of treatment with supportive therapy when appropriate is generally adequate.

In cases involving blood dyscrasias, the affected parameters should be monitored and phenylbutazone treatment ceased. Some blood dyscrasias may be irreversible.
Where there is gastro-intestinal involvement, cease phenylbutazone treatment and treat with cimetidine, antacids and fluid therapy.
Following overdose, irreversible renal damage has also been reported.

4.11 Withdrawal Period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Summary Presentation of the Active Ingredient

Phenylbutazone is a non-steroidal anti-inflammatory drug (NSAID) of the pyrazolone group.

5.1 Pharmacodynamic properties

Cyclo oxygenase is the enzyme responsible for the conversion of arachidonic acid into pro-inflammatory prostanoid mediators.
Phenylbutazone works by inhibition of this cyclo oxygenase activity and hence inhibits prostaglandin formation. A major metabolite, Oxyphenbutazone, has a similar effect.
As a result, phenylbutazone is apotent anti-inflammatory and analgesic.

5.2 Pharmacokinetic properties

Phenylbutazone is rapidly metabolised (half life 3-6 hrs). Its major metabolite, Oxyphenbutazone, produced within the body by hydroxylation, is also rapidly metabolised and eliminated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coating
Titanium Dioxide
Syrup
Purified Talc
Maize Starch

Core
Potato Starch
Sodium Lauryl Sulphate
Gelatin
Syrup
Sodium Starch Glycollate Type A

Silica Colloidal Anhydrous
Magnesium Stearate
Alginic Acid
Purified Talc

Other Ingredients
Water, Purified

6.2 Major Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

White cylindrical polypropylene containers (securitainer) with white, tamper-evident, snap-top polyethylene closure containing 250, 500 or 1000 tablets.
Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Ayrton Saunders Limited
9 Arkwright Road
Astmoor Industrial Estate
Runcorn
Cheshire
WA7 1NU

8. MARKETING AUTHORISATION NUMBER

Vm 16431/5002

9. DATE OF THE FIRST AUTHORISATION

26 April 1998

10. DATE OF REVISION OF THE TEXT

November 2022

Approved 25 November 2022