PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Phenylbutazone 200mg Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains: Phenylbutazone 200mg.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

500/1000

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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.
For dogs weighing from 5-20kg the use of Phenylbutazone 100mg tablets is indicated.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings

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.

For further information – see package leaflet.

Contraindications

Phenylbutazone 200mg should not be administered to dogs weighing less than 20kg bodyweight. Do not exceed the stated dose or the duration of treatment.

Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is evidence of a blood dyscrasia or hypersensitivity to the product.

Do not administer other NSAID's concurrently or within 24 hours of each other. Some NSAID's may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.
Not to be used in cats.

10. EXPIRY DATE

Coded on during production.

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of used packaging in the household refuse. Unused tablets should be returned to the veterinary surgeon.

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

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

Only to be dispensed by veterinarians, in secure child resistant containers.

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

Keep out of the reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ayrton Saunders Ltd. Runcorn, England.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 16431/5002

17. MANUFACTURER'S BATCH NUMBER

Coded on during production.

PACKAGE LEAFLET FOR: PHENYLBUTAZONE 200mg TABLETS

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

Name and address of M.A. Holder
Ayrton Saunders Ltd.,
9 Arkwright Road,
Astmoor Industrial Estate,
Run corn, Cheshire, WA7 1 NU.

Name and address of Manufacturer
Norbrook laboratories Ltd.,
Station Works, Newry,
Co. Down, BT35 6J P.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PHENYLBUTAZONE 200mg TABLETS

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

White sugar coated tablets containing Phenylbutazone 200 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is evidence of a blood dyscrasia or hypersensitivity to the product.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Dogs

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

Dosage and administration
For oral administration only. 20 mg/kg daily for 7 days preferably in divided doses every 8 or 12 hours, followed by 10 mg/kg daily for 7 days preferably in divided doses every 8 or 12 hours.
Phenylbutazone 200 mg should not be administered to dogs of less than 20 kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

The tablets should be administered whole with or immediately after food. In older dogs suffering chronic musculo-skeletal disease the course of treatment at the lower dose may be extended but the patient must be regularly monitored for any possible adverse effects.
In the case of trauma, if symptoms persist after the initial two week course of treatment the diagnosis should be reassessed.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store in a dry place.
Do not store above 25°C.

12. SPECIAL WARNING(S)

User Warnings

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.

Phenylbutazone 200 mg should not be administered to dogs weighing less than 20 kg bodyweight.
Do not exceed the stated dose or the duration of treatment.

Do not administer other NSAID's concurrently or within 24 hours of each other. Some NSAID's may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

NSAID's can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections, appropriate antimicrobial therapy should be instigated.

Not to be used in cats.

Use in animal 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 and careful clinical management.

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

Concurrent administration of potential nephrotoxic drugs should be avoided.

In suspect cases 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.

It is preferable that NSAID's which inhibit prostaglandin synthesis are not administered to animals undergoing anaesthesia until fully recovered.

For animal treatment only.

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

Dispose of used packaging in the household refuse. Unused tablets should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2022

15. OTHER INFORMATION

POM V

To be supplied only on veterinary prescription.

Package Quantities
Containers of 250, 500 and 1000 Tablets.

Further information
For dogs weighing less than 20 kg and more than 5 kg the use of Phenylbutazone 100 mg is indicated.

Marketing authorisation number
Vm 16431/5002

Approved 25 November 2022