PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epilease 250 mg Capsules for dogs
Potassium bromide

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each capsule contains 250mg of Potassium Bromide.

3. PHARMACEUTICAL FORM

Capsule, hard

4. PACKAGE SIZE

60 Capsules

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use. Administer with food.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings

- Do not break capsules.
- Do not use this product if you have known sensitivity to bromide.
- Wash hands thoroughly after use.
- Read package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

12. DISPOSAL

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

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

POM-V

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

VetPlus Ltd
Animal House
Boundary Road
Lytham
Lancashire
FY8 5LT

16. MARKETING AUTHORISATION NUMBER

Vm 18182/4002

17. MANUFACTURER'S BATCH NUMBER

Batch No. <number>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epilease 250 mg Capsules for dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

VetPlus Ltd

3. EXPIRY DATE

EXP <month/year>

4. BATCH NUMBER

BN <number>

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET FOR EPILEASE 250 MG:

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

VetPlus Ltd
Animal House
Boundary Road
Lytham
Lancashire
FY8 5LT

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epilease 250 mg Capsules, for dogs

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

Each capsule contains 250 mg of Potassium Bromide
Orange and blue coloured hard gelatine capsule

4. INDICATION(S)

This product is indicated for use as an anti-epileptic therapy adjunct to phenobarbital in refractory cases of epilepsy in dogs.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to bromide, or to any of the excipients.
Do not use in severe renal insufficiency.

6. ADVERSE REACTIONS

Common adverse reactions are somnolence, ataxia (hind end weakness and loss of coordination), polyuria, polydipsia, nausea which may be accompanied by vomiting, pancreatitis and erythematous dermatitis (bromide rash).

Uncommon adverse reactions are behavioural changes such as irritability or restlessness.

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).

Side effects may appear in dogs on higher doses of therapy, and symptoms usually disappear after the dose is decreased. If the dog appears too sedated, assess the serum concentrations of both bromide and phenobarbital to determine whether the dose of either should be reduced.
If potassium bromide dose is reduced, serum bromide concentrations should be monitored in order to ensure that they fall within the therapeutic range. If you notice

any serious effects or other effects not mentioned in the package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

For oral use. Administer with food.
The dose should be titrated to the individual dog as the required dosage and serum bromide concentration will vary between individual animals

9. ADVICE ON CORRECT ADMINISTRATION

Administer with food at an initial dose of 15 mg/kg bodyweight twice daily (equivalent to a total daily dose of 30 mg/kg). Twice daily administration is advised in order to reduce the risk of gastrointestinal disturbances. Due to the 24 day half-life of bromide, it can take several weeks or months to achieve steady-state serum concentrations.

At the beginning of treatment, serum bromide levels should be checked regularly, e.g. at 4, 8 and 12 weeks after the first dose. The expected therapeutic serum bromide concentration (when used in conjunction with phenobarbital) is 800 to 2000 µg/ml. Adjustments to the dose should be made with regard to the frequency of seizures, the half-life of bromide and the serum bromide concentration.

Long term monitoring of serum bromide (and associated phenobarbital) concentrations should be performed as clinically justified by the individual case.

Use in dogs with a bodyweight of less than 16.67 kg should be subject to a risk/benefit assessment (see section 12).

It is recommended to administer a reduced initial starting dose to dogs with mild or moderate renal insufficiency, with more frequent monitoring of serum bromide levels (see section 12).

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C

12. SPECIAL WARNING(S)

Special warnings for each target species
The concentration of bromide in serum, the clinical response and the therapeutic effect of administration of the product vary between individuals (see section 9)

A high chloride intake can increase the elimination of bromide (see 'Interaction with other medicinal products and other forms of interaction' below). Therefore, whilst it is not necessary for dogs receiving this product to be on a low salt diet, an increase in the dog's salt intake may require an adjustment in bromide dose. The salt content of a dog's diet during the treatment period should not be altered drastically, and should be maintained at a stable level. It is advisable not to change the dog's diet during therapy.

i. Special precautions for use in animals

Do not abruptly discontinue therapy as this may precipitate seizures.

This product should be used with caution in dogs with mild or moderate renal insufficiency, since excretion of bromide is reduced (see section 5 & 'overdose' below). To prevent bromide accumulation and a relative overdose of bromide, administer a reduced dose and monitor the serum bromide concentration closely. A reduction in chloride intake could cause bromide intoxication (see 'Interaction with other medicinal products and other forms of interaction' and 'overdose' below).

Dogs weighing less than 16.67 kg cannot be accurately dosed with the recommended initial dose rate of 15 mg/kg twice daily as the minimum dose achievable is 500 mg per day as two 250 mg capsules (see section 9).

Close monitoring for adverse reactions is advisable at higher serum bromide concentrations.

Administration on an empty stomach may induce vomiting.

Potentially severe side effects can be associated with the use of potassium bromide in cats.

ii. User Warnings

People with a known hypersensitivity to bromide should avoid contact with this product.
Do not break or divide capsules.
The contents of the capsules may cause skin irritation, including itchiness, rash, peeling, flaking or redness of the skin.
In the event of accidental breakage of capsules and contact of the contents with the skin, wash immediately with plenty of water.
Seek medical attention if irritation persists, showing the physician the carton or package leaflet.
This product may be harmful upon ingestion and can cause adverse effects such as nausea and vomiting.
Care should be taken to avoid accidental ingestion.
In case of accidental ingestion, seek medical attention immediately and show the physician the carton or package leaflet.
Wash hands thoroughly immediately after handling and/or administering the product.

To the physician:
Bromide intoxication can be treated by administration of sodium chloride or a suitable chloruretic agent.

Interaction with other medicinal products and other forms of interaction

Bromide and chloride compete for reabsorption by the kidneys. Increasing dietary chloride (salt) intake will decrease reabsorption of bromide by the kidneys, causing decreased serum bromide concentrations, which could lead to seizures. Conversely, changing to a diet low in chloride will cause bromide levels to increase, which could cause bromide intoxication (see section 12i and 'overdose' below).

Loop diuretics (e.g. furosemide) can increase bromide excretion and can lower the level of bromide in the blood.

Administration of fluids or drug formulations containing chloride can lower serum bromide concentrations.

Bromide is synergistic with other GABA-ergic drugs such as phenobarbital.

Overdose (symptoms, emergency procedures, antidotes)

Bromide toxicity is uncommon. It can occur in dogs with renal insufficiency or those that are on a very high dose of bromide (see sections 9 & 12i). However, an overdose of this product can produce brominism, characterised by ataxia, somnolence, nausea and pancreatitis (i.e. symptoms similar to those listed in section 6).

If overdose is suspected, the dosage of the product should be reduced immediately, with close monitoring of bromide serum concentrations in order to establish an appropriate therapeutic level.

In cases of overdose, if necessary and appropriate, 0.9% sodium chloride may be used intravenously to reduce serum bromide concentrations.

Use during pregnancy, lactation or lay

Bromide transfer to the offspring occurs when administered in high amounts to dam rats in early pregnancy, with detrimental effects on the offspring. In the absence of studies to demonstrate the safety of bromide in pregnant and lactating bitches when used at the recommended doses, the product should not be used in these animals.

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

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

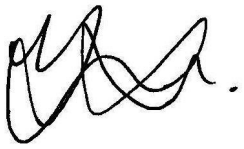
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

15. OTHER INFORMATION

For Animal Treatment Only
Pack sizes of 60 capsules
Distribution Category: POM-V
Vm No. 18182/4002



Approved: 12 April 2022