1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Libromide 325 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Potassium bromide 325 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Microcrystalline cellulose
Magnesium stearate
Stearic acid
Saccharin sodium

Plain white circular biconvex 9.5 mm tablet with a single scored line on one face.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

An anti-epileptic agent for use as an adjunct to phenobarbital in the control of refractory cases of epilepsy in dogs.

3.3 Contraindications

Do not use in dogs with severe renal insufficiency.
Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.

3.4 Special warnings

It is advisable not to change the dog's diet during therapy due to the effect of chloride intake on serum bromide concentrations, see section 3.8.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not abruptly discontinue therapy as this may precipitate seizures.
In renal insufficiency, excretion of bromide is reduced. To prevent bromide accumulation, and a relative overdose of potassium bromide (see section 3.10), administer a reduced dose of the veterinary medicinal product and monitor the serum bromide concentration closely.
A reduction in chloride intake could cause bromide intoxication (see section 3.8).
Administration on an empty stomach may induce vomiting.

Dogs weighing less than 11 kg cannot be accurately dosed with the recommended initial dose rate of 15 mg/kg twice daily as the minimum dose achievable by division of the veterinary medicinal product is 162.5 mg, see section 3.9.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not handle this product if you are pregnant, think you are pregnant or if you are breast feeding.
People with known hypersensitivity to bromide should avoid contact with the veterinary medicinal product.
Wash hands thoroughly immediately after breaking or handling any tablets.
Discontinue handling the veterinary medicinal product if you develop any signs of skin irritation, including itchiness, rash, peeling or flaking of skin or redness. In case of irritation of the skin or eyes, or in case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Special precautions for the protection of the environment:
Not applicable.

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

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	High pancreatic-specific lipase[a] Dermatitis (bromide rash)[b] Polyuria Polyphagia, polydipsia Vomiting, nausea Somnolence, ataxia[c]
Uncommon (1 to 10 animals / 1 000 animals treated):	Behavioural disorders (e.g. restlessness, irritability)
Rare (1 to 10 animals / 10 000 animals treated):	Diarrhoea[d]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Pancreatitis[b], haemorrhagic diarrhoea Anorexia Sedation[e] Hepatopathy Dyspnoea Vocalisation

[a] In dogs receiving potassium bromide in combination with phenobarbital. This may or may not be associated with clinical signs of pancreatitis.

[b] Symptomatic therapy may be required.
[c] Hind end weakness and loss of coordination.
[d] Transient.
[e] If the dog is too sedated, assess the serum concentrations of both bromide and phenobarbital to determine whether the dose of either should be reduced.

Adverse clinical signs which may appear in dogs on higher doses of therapy usually disappear following a reduction in dose. If the dose is reduced, measure the serum bromide concentration to ensure it remains within the therapeutic range.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation in dogs. Although there was no evidence of reproductive toxicity in laboratory animals, bromide can cross the placenta and cases of neonatal bromide toxicity have been reported in humans. In the absence of specific data, continued use during pregnancy should be subject to a benefit/risk assessment by the responsible veterinarian.
Since bromide may be excreted into milk, monitor nursing puppies for somnolescence/sedative effects; if necessary, consider early weaning, or an artificial suckling method.

3.8 Interaction with other medicinal products and other forms of interaction

Bromide and chloride compete for re-absorption by the kidneys. Increasing dietary chloride (salt) intake will decrease renal re-absorption of bromide, causing decreased serum bromide concentrations, which could lead to seizures. Conversely, changing to a diet low in chloride will increase serum bromide concentrations, which could cause bromide intoxication (see section 3.10).
Loop diuretics (e.g. furosemide) can increase bromide excretion, lowering serum bromide concentrations.
Administration of fluids or drug formulations containing chloride can lower serum bromide concentrations.
Bromide is synergistic with other GABA-ergic drugs such as phenobarbital.

3.9 Administration routes and dosage

Oral use. Administer with food.
Administer to dogs with refractory epilepsy, where seizure control is unsatisfactory despite appropriate phenobarbital therapy, when serum phenobarbital concentrations are at a steady-state within the therapeutic range.
The dose should be titrated to the individual dog as the required dosage will depend on the nature and severity of the underlying disease.
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.
The tablets can be divided into halves.
Due to the 24 day half-life of bromide, it can take several weeks or months to achieve steady-state serum concentrations. For at least the first three months following commencement of therapy, measure serum bromide concentrations every 4 weeks. 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.

Close monitoring for side effects is advisable at higher serum bromide concentrations.
Use in dogs with a body weight of less than 11 kg should be subject to a risk/benefit assessment, see section 3.5.
To ensure a correct dosage, body weight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Clinical signs of bromide toxicity, such as ataxia, somnolescence, nausea and pancreatitis may occur in dogs when a high dose is administered.
If overdose is suspected, immediately reduce the dosage. Closely monitor the serum bromide concentration in order to establish an appropriate therapeutic concentration.
In cases of overdose, if necessary and appropriate, administer 0.9% sodium chloride solution intravenously to reduce serum bromide concentrations.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QN03AX91

4.2 Pharmacodynamics

Potassium bromide is a halide anticonvulsant. Bromide replaces chloride in all body fluids. It competes with chloride transport across nerve cell membranes and inhibits sodium transport and so causes membrane hyperpolarisation. This hyperpolarisation raises the seizure threshold and prevents the spread of epileptic discharges. Bromide has effects on active transport across glial cell membranes and affects passive movements of ions by competition with chloride for anion channels in post-synaptic membranes that are activated by inhibitory neurotransmitters. This potentiates the effect of GABA which results in a synergistic activity of bromide with other drugs that have GABA-ergic activity.

4.3 Pharmacokinetics

The pharmacokinetics of potassium bromide have been studied in dogs. The half-life is approximately 24 days. Due to this extremely long half life, it can take several weeks/months to achieve steady state concentrations. Potassium bromide is well absorbed orally with peak absorption in about 1.5 hours. Once ingested, the potassium bromide salt dissociates, and the bromide ion is rapidly absorbed by the gastrointestinal tract.
After absorption, the bromide ion rapidly distributes, as does chloride, throughout the extra-cellular space and into cells. Chloride is distributed passively across most cell membranes according to the trans-membrane potential, and it is likely that bromide distributes in the same manner. As the bromide concentration is increased in the body, the concentration of chloride is decreased in direct proportion to the increase in bromide.
Bromide is not metabolised by the body, it enters and leaves the body only as the monovalent anion. Excretion of bromide is mainly via the kidneys, where it competes with chloride for tubular reabsorption.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.
Use any halved tablet within 12 hours.

5.3 Special precautions for storage

Do not store above 25 °C.
Keep the container tightly closed in order to protect from moisture.

5.4 Nature and composition of immediate packaging

Pack sizes: 100 and 500 tablets.
White, opaque polypropylene cylindrical pots, with white, opaque polyethylene child resistant or tamper evident lids.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V

7. MARKETING AUTHORISATION NUMBER(S)

VPA22622/015/001

8. DATE OF FIRST AUTHORISATION

18/11/2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10/04/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).