

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Bag of 200 g and 1 Kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dobroxine 500 + 50 mg/g powder for use in drinking water/milk for calves

2. COMPOSITION

Each g contains:

Active substances:

Doxycycline	500.0 mg
(as doxycycline hyclate	596.0 mg)
Bromhexine hydrochloride	50.0 mg

Light yellow powder.

3. PACKAGE SIZE

Bag of 200 g and 1 Kg.

4. TARGET SPECIES

Cattle (pre-ruminant calves).

5. INDICATIONS FOR USE

Indications for use

Cattle (pre-ruminant calves): Treatment of respiratory infections caused by *Pasteurella multocida* and *Mannheimia haemolytica* sensitive to doxycycline.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypersensitivity to tetracyclines, to bromhexine or to any of the excipient(s).
Do not use in animals with hepatic dysfunction.
Do not use in animals with functional rumen.

7. SPECIAL WARNINGS

Special warnings

As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

The use of the veterinary medicinal product in conditions other than those recommended in the Summary of Product Characteristics may increase the prevalence of bacteria resistant to doxycycline and decrease the efficacy of treatment with tetracyclines as a consequence of cross-resistance.
Avoid its administration in rusty drinkers.

This veterinary medicinal product does not contain any antimicrobial preservative.

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

- This veterinary medicinal product may cause hypersensitivity reactions (allergy). People with known hypersensitivity to tetracyclines or bromhexine should avoid contact with the veterinary medicinal product.
- This veterinary medicinal product may produce adverse effects or cause irritation to the skin, eyes and mucous membranes.
- Handle the veterinary medicinal product with care to avoid production of dust and inhalation of dust particles as well as contact with skin and eyes.
- Personal protective equipment consisting of impervious gloves, overalls, approved safety goggles and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143) should be worn when handling the veterinary medicinal product.
- Do not smoke, eat or drink while handling the veterinary medicinal product.
- In case of contact, rinse eyes with plenty of clean water and skin with soap and water.
- If you develop symptoms following exposure such as skin rash, seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes, or difficulty in breathing are more serious symptoms and require urgent medical attention.
- Wash hands after use.

Pregnancy and lactation:

Not applicable.

Interactions with other medicinal products and other forms of interaction:

The absorption of doxycycline can be reduced in the presence of high amounts of calcium, iron, magnesium or aluminum in the diet. Do not administer together with antacids, kaolin and iron preparations.

Overdose:

Not described.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water or liquid feed containing biocidal products, feed additives or other substances used in drinking water.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

Adverse events

Cattle (pre-ruminant calves).

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic reaction. Photosensitivity. ¹ Digestive tract disorder.
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¹ Due to a intestinal dysbiosis.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Administration in milk.

Cattle (pre-ruminant calves): 10 mg of doxycycline (hyclate) + 1 mg of bromhexine hydrochloride/kg bodyweight/day, for 4-5 consecutive days equivalent to 20 mg of the product/kg bodyweight/day.

Taking into account the dose to administer and the number and weight of the animals, it is possible to calculate the exact daily amount of veterinary medicinal product.

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

The use of suitably calibrated measuring equipment is recommended if part of the packs are used.

The concentration of the veterinary medicinal product per litre of milk replacer should be calculated according to the following formula:

$$\text{mg of veterinary medicinal product per litre of milk replacer} = \frac{\text{mg veterinary medicinal product/kg b.w./day} \times \text{mean body weight (kg) of animals to be treated}}{\text{Mean daily milk replacer intake/animal (l)}}$$

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Once reconstituted with milk, the solution should be consumed within 6 hours.
The use of suitably calibrated weighing equipment is recommended if part of containers is used.

11. WITHDRAWAL PERIODS

Withdrawal periods

Cattle (pre-ruminant calves):
Meat and offal: 16 days
Not authorised for use in animals producing milk for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes

200 g bag
1 Kg bag

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS KARIZOO, S.A.
Pol. Ind. La Borda, Mas Pujades 11-12
08140 Caldes de Montbui (Barcelona)
Spain

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

18. OTHER INFORMATION

Other information

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: 6 months
Shelf life after dissolution in milk replacer according to directions: 6 hours.

21. BATCH NUMBER

Lot {number}