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

Authorised

- Bromhexine hydrochloride
- Doxycycline hyclate

Product identification

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

Active substance:
Bromhexine hydrochloride

Doxycycline hyclate

Target species:
Cattle (pre-ruminant)

Route of administration:
In drinking water/milk use

Product details

Active substance and strength:
Bromhexine hydrochloride
50.00 milligram(s) / 1.00 gram(s)

Doxycycline hyclate
596.00 milligram(s) / 1.00 gram(s)

Pharmaceutical form:
Powder for use in drinking water/milk

Withdrawal period by route of administration:
In drinking water/milk use:

- **Cattle (pre-ruminant)**
  - Meat and offal. 16 day

- **Cattle (pre-ruminant)**
  - Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01AA20

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Portugal

Package description:
Bag of 200 g
Bag of 1 Kg

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - known active substance (Article 8 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Laboratorios Karizoo S.A.

Marketing authorisation date:
27/05/2025

Manufacturing sites for batch release:
Laboratorios Karizoo S.A.

Responsible authority:
Directorate General For Food And Veterinary

Authorisation number:
1709/01/25DFVPT.

Date of authorisation status change:
28/05/2025

Reference member state:
Spain

Procedure number:
ES/V/0446/001

Concerned member states:
Cyprus Italy Netherlands Portugal

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Combined File of all Documents

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Summary of Product Characteristics

Labelling

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