

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

This document does not exist in this language (English). You can find it in another language below.

Summary of Product Characteristics

Labelling

eu-PUAR-esv0446001-dcp-dobroxine-500-mg-g-+-50-mg-g-powder-for-use-in-drinking-water-milk-for-calves-en.pdf