

Bimacox 2.5 mg/ml Oral Suspension for Sheep and Cattle

Authorised

- Diclazuril

Product identification

Medicine name:

Bimacox 2.5 mg/ml Oral Suspension for Sheep and Cattle

Active substance:

Diclazuril

Target species:

Cattle

Sheep

Route of administration:

Oral use

Product details

Active substance and strength:

Diclazuril

2.50 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Oral suspension

Withdrawal period by route of administration:**Oral use:**

-

Cattle

- Meat and offal. 0 day

-

Sheep

- Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QP51BC03

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

United Kingdom (Northern Ireland)

Package description:

1 litre high density polyethylene container with polypropylene tamper-evident cap with an aluminium seal.

2.5 litre high density polyethylene container with polypropylene tamper-evident cap with an aluminium seal.

5 litre high density polyethylene container with polypropylene tamper-evident cap with an aluminium seal.

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Hybrid application – bioavailability studies cannot be used to demonstrate bioequivalence (Article 19(1)(b) of Regulation (EU) 2019/6)

Marketing authorisation holder:

Bimeda Animal Health Limited

Marketing authorisation date:

22/08/2024

Manufacturing sites for batch release:

Bimeda Animal Health Limited

Responsible authority:

The Veterinary Medicines Directorate

Authorisation number:

Vm 50146/3004

Date of authorisation status change:

22/08/2024

Reference member state:

Ireland

Procedure number:

IE/V/0784/001

Concerned member states:

Austria Belgium Czechia Estonia France Germany Italy Latvia Lithuania
Poland Portugal Spain United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

Summary of Product Characteristics

ie-puar-mr-iev0784001-bimacox-25-mgml-oral-suspension-for-sheep-and-catt-en.pdf