

Qualimec 10 mg/ml Solution for Injection.

Authorised

- Ivermectin

Product identification

Medicine name:

Qualimec 10 mg/ml Solution for Injection.

Active substance:

Ivermectin

Target species:

Cattle

Sheep

Pig

Route of administration:

Subcutaneous use

Product details

Active substance and strength:

Ivermectin

10.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Subcutaneous use:

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Cattle

- Meat and offal. 49 day

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Sheep

- Meat and offal. 42 day

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Pig

- Meat and offal. 28 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QP54AA01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Ireland

Package description:

Clear PET multidose container with bromobutyl rubber stopper and aluminium cap.

Pack size 50 ml

HDPE multidose container with bromobutyl rubber stopper and aluminium cap. Pack size: 200 ml

Clear PET multidose container with bromobutyl rubber stopper and aluminium cap.

Pack size 500 ml

HDPE multidose container with bromobutyl rubber stopper and aluminium cap. Pack size: 500 ml.

HDPE multidose container with bromobutyl rubber stopper and aluminium cap. Pack size: 50 ml

Clear PET multidose container with bromobutyl rubber stopper and aluminium cap.
Pack size 250 ml

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Well-established use application (Article 13a of Directive No 2001/82/EC)

Marketing authorisation holder:

Eco Animal Health Europe Limited

Marketing authorisation date:

31/12/1899

Manufacturing sites for batch release:

Produlab Pharma B.V.

Divasa Farmavic S.A.

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA22693/002/001

Date of authorisation status change:

31/12/1899

Reference member state:

Ireland

Procedure number:

IE/V/0145/001

Concerned member states:

France Germany Greece Hungary Italy Luxembourg Netherlands Portugal
Spain United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

Combined File of all Documents