

Qualimec 10 mg/ml Solution for Injection.

Authorised

- Ivermectin

Product identification

Medicine name:

Qualimec 10 mg/ml Solution for Injection.

Ivermax 10 mg/ml oplossing voor injectie

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:**

-

Cattle

- Meat and offal. 49 day

-

Sheep

- Meat and offal. 42 day

-

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:

Netherlands

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:

12/01/2007

Manufacturing sites for batch release:

Produlab Pharma B.V.

Divasa Farmavic S.A.

Responsible authority:

Medicines Evaluation Board

Authorisation number:

REG NL 10446

Date of authorisation status change:

26/01/2022

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

Combined File of all Documents

English (PDF)

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Summary of Product Characteristics