File downloaded on 2026-11-25
Source URL: https://medicines.health.europa.eu/veterinary/en/600000048712

Premadex 10 mg/ml Solution for Injection

Authorised

- Ivermectin

Product identification

Medicine name:
Premadex 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:

- **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:

United Kingdom (Northern Ireland)

Package description:

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

HDPE 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: 500 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: 200 ml

Clear PET multidose container with bromobutyl rubber stopper and aluminium cap.
Pack size 50 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:
17/05/2007

Manufacturing sites for batch release:
Divasa Farmavic S.A.
Produlab Pharma B.V.

Responsible authority:
The Veterinary Medicines Directorate

Authorisation number:
Vm 61471/3001

Date of authorisation status change:
2/06/2023

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