Kelamoxil LA 150 mg/ml suspension for injection for cattle and pig

Authorised

- Amoxicillin

Product identification

Medicine name:
Kelamoxil LA 150 mg/ml suspension for injection for cattle and pig
Kelamoxil LA 150 mg/ml Stungulyf, dreifa handa nautgripum og svínum

Active substance:
Amoxicillin

Target species:
Cattle
Pig

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Amoxicillin
150.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Suspension for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - Meat and offal. 18 day
  - Milk. 72 hour
- **Pig**
  - Meat and offal. 20 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01CA04

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Iceland

Package description:

Clear PET vial of 250 ml closed with type I laminated chlorobutyl rubber stopper and aluminium cap in a carton box
Clear PET vial of 100 ml closed with type I laminated chlorobutyl rubber stopper and aluminium cap in a carton box
Clear type II glass vial of 250 ml closed with type I laminated chlorobutyl rubber stopper and aluminium cap in a carton box.
Clear type II glass vial of 100 ml closed with type I laminated chlorobutyl rubber stopper and aluminium cap in a carton box.

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 18 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Kela Kempisch Laboratorium Kela Laboratoria

Marketing authorisation date:
31/08/2023

Manufacturing sites for batch release:
Kela - Kempisch Laboratorium - Kela Laboratoria

Responsible authority:
Icelandic Medicines Agency

Authorisation number:
IS/2/23/013/01

Date of authorisation status change:
31/08/2023

Reference member state:
Netherlands

Procedure number:
NL/V/0390/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

This information is not available for this product.

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

Documents

Summary of Product Characteristics

Package Leaflet and Labelling

NLV0390001DC_DCP_Kelamoxil LA Final PuAR.pdf
