Ketosol-100, 100 mg/ml solution for injection for cattle, pigs and horses

Authorised

- Ketoprofen

Product identification

Medicine name:
Ketosol-100, 100 mg/ml solution for injection for cattle, pigs and horses
Ketoject 100 mg/ml Roztwór do wstrzykiwań

Active substance:
Ketoprofen

Target species:
Cattle
Pig
Horse

Route of administration:
Intramuscular use
Intravenous use

Product details

Active substance and strength:

Ketoprofen
100.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 4 day
  - Milk. 0 hour
- **Pig**
  - Meat and offal. 4 day

Intravenous use:

- **Cattle**
  - Meat and offal. 4 day
  - Milk. 0 hour
- **Horse**
  - Meat and offal. 4 day

Not authorized for use in mares producing milk for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QM01AE03

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Poland

Package description:
50 ml amber glass bottles (type II) closed with brombutyl rubber stopper and aluminium cap or flip-off cap with aluminium seal and polypropylene cover.
100 ml amber glass bottles (type II) closed with brombutyl rubber stopper and aluminium cap or flip-off cap with aluminium seal and polypropylene cover.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Interchemie Werken De Adelaar Eesti AS

Marketing authorisation date:
14/08/2018

Manufacturing sites for batch release:
Interchemie Werken De Adelaar Eesti AS

Responsible authority:
Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:
2806

Date of authorisation status change:
14/08/2018

Reference member state:
Estonia

Procedure number:

EE/V/0102/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Finland France Germany Greece Hungary Ireland Italy Latvia Luxembourg Netherlands Poland Portugal Romania Slovakia Slovenia Spain Sweden

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

Documents

Summary of Product Characteristics