

KELAPROFEN 100 mg/ml

Authorised

- Ketoprofen

Product identification

Medicine name:

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

KELAPROFEN 100 mg/ml

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. no withdrawal period

Meat and offal: IV: 1 day, IM: 2 days

-

Pig

- Meat and offal. 2 day

-

Cattle

- Milk. 0 hour

Intravenous use:

-

Cattle

- Meat and offal. no withdrawal period

Meat and offal: IV: 1 day, IM: 2 days

-

Horse

- Meat and offal. 1 day

-

Cattle

- Milk. 0 hour

-

Horse

- Milk. no withdrawal period

Milk: Its use is not authorized in animals whose milk is used 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:

Ireland

Available in:

Ireland

Package description:

box containing 12 vials of 250 ml
box containing 12 vials of 100 ml
box containing 12 vials of 50 ml
box containing 10 vials of 250 ml
box containing 10 vials of 100 ml
box containing 10 vials of 50 ml
box containing 6 vials of 250 ml
box containing 6 vials of 100 ml
box containing 6 vials of 50 ml
box containing 1 vial of 250 ml
box containing 1 vial of 100 ml
box containing 1 vial of 50 ml

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:

KELA Kempisch Laboratorium Kela Laboratoria

Marketing authorisation date:

24/02/2012

Manufacturing sites for batch release:

KELA Kempisch Laboratorium Kela Laboratoria

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA10981/012/001

Date of authorisation status change:

24/02/2012

Reference member state:

Spain

Procedure number:

ES/V/0160/001

Concerned member states:

Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland
France Germany Greece Hungary Ireland Italy Lithuania Luxembourg
Netherlands Norway Poland Portugal Romania Slovakia Sweden
United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to

www.adrreports.eu/vet

Documents

Summary of Product Characteristics

Package Leaflet

Labelling

Combined File of all Documents

eu-PUAR-esv0160001-dcp-kelaprofen--100-mg-ml-en.pdf