

EMDOFLUXIN 50 MG/ML SOLUTION FOR INJECTION FOR CATTLE, HORSES AND PIGS

Authorised

- Flunixin meglumine

Product identification

Medicine name:

EMDOFLUXIN 50 MG/ML SOLUTION FOR INJECTION FOR CATTLE, HORSES AND PIGS

Active substance:

Flunixin meglumine

Target species:

Cattle

Pig

Equid

Route of administration:

Intramuscular use

Intravenous use

Product details

Active substance and strength:

Flunixin meglumine

83.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

•

Cattle

- Meat and offal. 31 day

- Milk. 36 hour

•

Pig

- Meat and offal. 24 day

Intravenous use:

•

Cattle

- Meat and offal. 4 day

- Milk. 24 hour

•

Equid

- Meat and offal. 5 day

- Milk. no withdrawal period

Milk: Not authorised for use in mares producing milk for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QM01AG90

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Slovenia

Available in:

Slovenia

Package description:

Cardboard box containing 1 vial of 50 mL

Cardboard box containing 1 vial of 250 mL

Cardboard box containing 1 vial of 100 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:

Emdoka

Marketing authorisation date:

1/06/2020

Manufacturing sites for batch release:

Produlab Pharma B.V.

Responsible authority:

Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia

Authorisation number:

DC/V/0709/001

Date of authorisation status change:

1/06/2020

Reference member state:

France

Procedure number:

FR/V/0417/001

Concerned member states:

Austria Belgium Bulgaria Croatia Denmark Estonia Germany Hungary
Ireland Italy Latvia Lithuania Luxembourg Netherlands Slovenia 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

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Labelling

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents

eu-puar-frv0417001-mr-rpe564-en.pdf