Profexx 50 mg/ml solution for injection for cattle

Authorised

- Carprofen
- Carprofen

Product identification

Medicine name:
Profexx 50 mg/ml solution for injection for cattle
Profexx 50 mg/ml injekčný roztok pre hovädzí dobytok

Active substance:
Carprofen
Carprofen

Target species:
Cattle
Cattle

Route of administration:
Subcutaneous use
Intravenous use

Product details

Active substance and strength:
Carprofen

50.00 milligram(s) / 1.00 millilitre(s)

Carprofen
50.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:

Subcutaneous use:

- **Cattle**
  - Meat and offal. 21 day
  - Milk. no withdrawal period zero hours

Intravenous use:

- **Cattle**
  - Meat and offal. 21 day
  - Milk. no withdrawal period zero hours

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QM01AE91

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

Authorisation status:
Valid

Authorised in:
Slovakia

Package description:
Cardboard box containing one clear glass (type II) vial of 100 ml with a grey bromobutyl rubber stopper and aluminium cap

Cardboard box containing one clear glass (type II) vial of 250 ml with a grey bromobutyl rubber stopper and aluminium cap
Cardboard box containing one clear glass (type II) vial of 50 ml with a grey bromobutyl rubber stopper and aluminium cap

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
Alfasan Nederland B.V.

Marketing authorisation date:
30/04/2024

Manufacturing sites for batch release:
Alfasan Nederland B.V.

Responsible authority:
Institute For State Control Of Veterinary Biologicals And Medicaments

Authorisation number:
96/008/DC/24-S

Date of authorisation status change:
30/04/2024

Reference member state:
Netherlands

Procedure number:
NL/V/0409/001

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)

Generic of:
600000047468

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

Documents

Combined File of all Documents

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