DRAXXIN PLUS

Authorised

- Ketoprofen
- Tulathromycin

Product identification

Medicine name:
DRAXXIN PLUS
DRAXXIN PLUS 100 mg/ml + 120 mg/ml soluție injectabilă pentru bovine

Active substance:
Ketoprofen
Tulathromycin

Target species:
Cattle

Route of administration:
Subcutaneous use

Product details

Active substance and strength:
Ketoprofen
120.00 milligram(s) / 1.00 millilitre(s)
Tulathromycin
100.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Subcutaneous use:

- **Cattle**
  - Milk. no withdrawal period

Not authorised for use in cattle producing milk for human consumption. Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

- Meat and offal. 50 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01FA99

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

Authorisation status:
Valid

Authorised in:
Romania

Available in:
Romania

Package description:
cardboard box containing 1 vial of 250 ml
cardboard box containing 1 vial of 100 ml
cardboard box containing 1 vial of 50 ml

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:
Fixed combination application (Article 13b of Directive No 2001/82/EC)

Marketing authorisation holder:
Zoetis Belgium

Marketing authorisation date:
26/11/2020

Manufacturing sites for batch release:
Zoetis Manufacturing & Research Spain S.L.

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:
250092

Date of authorisation status change:
1/07/2025

Reference member state:
Spain

Procedure number:
ES/V/0352/001

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

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eu-PUAR-draxxin-plus-en.pdf