

# DRAXXIN PLUS

Authorised

- Ketoprofen
- Tulathromycin

## Product identification

**Medicine name:**

DRAXXIN PLUS

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**Active substance:**

Ketoprofen

Tulathromycin

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**Target species:**

Cattle

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**Route of administration:**

Subcutaneous use

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## Product details

**Active substance and strength:**

Ketoprofen

120.00 milligram(s) / 1.00 millilitre(s)

Tulathromycin

100.00 milligram(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Solution for injection

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**Withdrawal period by route of administration:**

**Subcutaneous use:**

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**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

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QJ01FA99

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Romania

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**Available in:**

Romania

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**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

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Fixed combination application (Article 13b of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Zoetis Belgium

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**Marketing authorisation date:**

26/11/2020

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**Manufacturing sites for batch release:**

Zoetis Manufacturing & Research Spain S.L.

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**Responsible authority:**

Institute For Control Of Biological Products And Veterinary Medicines

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**Authorisation number:**

250092

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**Date of authorisation status change:**

1/07/2025

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**Reference member state:**

Spain

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**Procedure number:**

ES/V/0352/001

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**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)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Summary of Product Characteristics

Package Leaflet

Labelling

Combined File of all Documents

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