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Tolracol 50 mg/ml oral suspension for pigs, cattle and sheep

Authorised

Toltrazuril

Product identification

Medicine name:

Tolracol 50 mg/ml oral suspension for pigs, cattle and sheep

Tolracol 50 mg/ml Suspensie voor oraal gebruik

Tolracol 50 mg/ml Suspension buvable

Tolracol 50 mg/ml Suspension zum Einnehmen

Active substance:

Toltrazuril

Target species:

Cattle

Sheep

Pig

Route of administration:

Oral use

Product details

Active substance and strength:

Toltrazuril

Pharmaceutical form:

Oral suspension

Withdrawal period by route of administration:

Oral use:

•

Cattle

- Meat and offal. 63 day

•

Sheep

- Meat and offal. 42 day

•

Pig

- Meat and offal. 77 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QP51AJ01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Belgium

Available in:

Belgium

Package description:

Bottle (HDPE), closure (HDPE), sealing liner (LDPE): 250 ml of oral suspension, in a box.

Bottle (HDPE), closure (HDPE), sealing liner (LDPE): 1000 ml of oral suspension.

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:

KRKA tovarna zdravil d.d. Novo mesto

Marketing authorisation date:

27/01/2015

Manufacturing sites for batch release:

KRKA tovarna zdravil d.d. Novo mesto

Responsible authority:

Federal Agency For Medicines And Health Products

Authorisation number:

BE-V468746

Date of authorisation status change:

27/01/2015

Reference member state:

Ireland

Procedure number:

IE/V/0333/001

Concerned member states:

Belgium France Germany Italy Netherlands Portugal 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

English (PDF)

Published on: 3/05/2024

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Package Leaflet

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Labelling

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