

MACROSYN 100 MG/ML SOLUTION FOR INJECTION FOR CATTLE, PIGS AND SHEEP

Authorised

- Tulathromycin

Product identification

Medicine name:

MACROSYN 100 MG/ML SOLUTION FOR INJECTION FOR CATTLE, PIGS AND SHEEP

Active substance:

Tulathromycin

Target species:

Sheep

Pig

Cattle

Route of administration:

Intramuscular use

Subcutaneous use

Product details

Active substance and strength:

Tulathromycin

100.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

-

Sheep

- Meat and offal. 16 day
- Milk. no withdrawal period

Not authorised for use in animals 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.

-

Pig

- Meat and offal. 13 day

Subcutaneous use:

-

Cattle

- Meat and offal. 22 day
- Milk. no withdrawal period

Not authorised for use in animals 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.

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01FA94

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Denmark

Package description:

box of one 50 ml vial

box of one 500 ml vial

box of one 250 ml vial

box of one 100 ml vial

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:

Bimeda Animal Health Limited

Marketing authorisation date:

7/09/2020

Manufacturing sites for batch release:

Bimeda Animal Health Limited

Responsible authority:

Danish Medicines Agency

Authorisation number:

63139

Date of authorisation status change:

7/09/2020

Reference member state:

France

Procedure number:

FR/V/0418/001

Concerned member states:

Austria Belgium Denmark Estonia Germany Ireland Italy Latvia Lithuania
Netherlands Poland Spain

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.

Combined File of all Documents

eu-puar-frv0418001-mr-rpe582-en.pdf