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:
Spain

Package description:
Available only in French
Available only in French
Available only in French
Available only in French

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:
9/09/2020

Manufacturing sites for batch release:
Bimeda Animal Health Limited

Responsible authority:
Spanish Agency Of Medicines And Medical Devices

Authorisation number:
3935 ESP

Date of authorisation status change:
10/09/2020

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

Labelling

This document does not exist in this language (English). You can find it in another language below.

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet

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