

PROTIVITY LYOPHILISATE AND SOLVENT FOR SUSPENSION FOR INJECTION FOR CATTLE

Authorised

- Mycoplasma bovis, strain N2805-1, Live

Product identification

Medicine name:

PROTIVITY LYOPHILISATE AND SOLVENT FOR SUSPENSION FOR INJECTION FOR CATTLE

Active substance:

Mycoplasma bovis, strain N2805-1, Live

Target species:

Cattle

Route of administration:

Subcutaneous use

Product details

Active substance and strength:

Mycoplasma bovis, strain N2805-1, Live
2200000.00 Colony forming unit / 1.00 Dose

Pharmaceutical form:

Lyophilisate and solvent for suspension for injection

Withdrawal period by route of administration:**Subcutaneous use:**

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Cattle

- All relevant tissues. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AE05

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Belgium

Available in:

Belgium

Package description:

Cardboard box containing 1 vial with 10 doses of lyophilisate and 1 vial with 20 ml solvent.

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Full application - New active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Zoetis Belgium

Marketing authorisation date:

10/07/2023

Manufacturing sites for batch release:

Zoetis Belgium

Responsible authority:

Federal Agency For Medicines And Health Products

Authorisation number:

BE-V661554

Date of authorisation status change:

10/07/2023

Reference member state:

France

Procedure number:

FR/V/0454/001

Concerned member states:

Austria Belgium Bulgaria Cyprus Czechia Denmark Estonia Finland
Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg
Netherlands Poland Portugal Romania Slovakia Spain Sweden
United Kingdom (Northern Ireland)

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.

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-frv0454001-mr-rpe758-en.pdf