Bultavo 3, Suspension for injection

Authorised

 Bluetongue virus, serotype 3, strain Bio-93:BTV3, Inactivated

Product identification

Medicine name:

Bultavo 3, Suspension for injection
BULTAVO 3 SUSPENSION INJECTABLE POUR OVINS ET BOVINS

Active substance:

Bluetongue virus, serotype 3, strain Bio-93:BTV3, Inactivated

Target species:

Sheep

Cattle

Route of administration:

Subcutaneous use Intramuscular use

Product details

Active substance and strength:

Bluetongue virus, serotype 3, strain Bio-93:BTV3, Inactivated 320.00 enzyme-linked immunosorbent assay unit / 1.00 Dose

Pharmaceutical form:

Withdrawal period by route of administration:

Subcutaneous use:

Sheep

- Meat and offal. 0 day
- Milk. 0 day

Intramuscular use:

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Cattle

- Meat and offal. 0 day
- Milk. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

Q102AA08

Q104AA02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription except for some pack sizes

Authorisation status:

Valid

Authorised in:

France

Package description:

Glass Vial 10 x 10.0 millilitre(s)

Glass Vial 1 x 10.0 millilitre(s)

Glass Vial 1 x 50.0 millilitre(s)

Glass Vial 1 x 100.0 millilitre(s)

Plastic (HDPE) Vial 10 x 10.0 millilitre(s)

Plastic (HDPE) Vial 1 x 10.0 millilitre(s)

Plastic (HDPE) Vial 1 x 50.0 millilitre(s)

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Applications in exceptional circumstances (Article 25 of Regulation (EU) 2019/6)

Marketing authorisation holder:

Boehringer Ingelheim Vetmedica GmbH

Marketing authorisation date:

14/05/2025

Manufacturing sites for batch release:

Bioveta a.s.

Responsible authority:

French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:

FR/V/5480517 0/2025

Date of authorisation status change:

14/05/2025

Reference member state:

Czechia

Procedure number:

CZ/V/0207/001

Concerned member states:

Austria Belgium Cyprus Denmark Finland France Germany Greece Ireland Italy Luxembourg Malta Netherlands Norway Portugal Spain Sweden United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Package Leaflet and 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.

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