BioBos BTV 3 suspension for injection for sheep and cattle

Authorised

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

Product identification

Medicine name:
BioBos BTV 3 suspension for injection for sheep and cattle

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:
Suspension for injection

Withdrawal period by route of administration:

Subcutaneous use:

- **Sheep**
  - Meat and offal. 0 day
  - Milk. 0 hour

Intramuscular use:

- **Cattle**
  - Milk. 0 hour
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI02AA08
QI04AA02

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

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Authorisation status:
Valid

Authorised in:
Slovenia

Package description:
Glass vial of hydrolytic class I 1 x 10 doses
Glass vials of hydrolytic class II 1 x 50 doses
Glass vials of hydrolytic class II 1 x 100 doses
HDPE vial 1 x 10 doses
HDPE vial 1 x 50 doses
HDPE vial 1 x 100 doses
Glass vial 10 x 10 doses

HDPE vial 10 x 10 doses

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:
Bioveta a.s.

Marketing authorisation date:
23/09/2025

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia

Authorisation number:
MR/V/0830/001

Date of authorisation status change:
8/10/2025

Reference member state:
Czechia

Procedure number:
CZ/V/0212/001

Concerned member states:
Bulgaria Estonia Hungary Latvia Lithuania Poland Slovakia Slovenia

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.

Labelling

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.

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