BLUEVAC-3®

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Product information

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC-3 suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Bluetongue virus (BTV), serotype 3, strain BTV-3/NET2023, inactivated ..... $10^{6.5}CCID_{50}$*

*$CCID_{50}$: 50% cell culture infective dose equivalent to titre prior inactivation.

Adjuvants:

Aluminium hydroxide ..... 6 mg

Purified saponin (Quil A) ..... 0.05 mg

Excipients:

Thiomersal (0.1 mg)

Sodium chloride

Disodium phosphate

Potassium phosphate

Water for injections

3. PHARMACEUTICAL FORM

Suspension for injection.
White or pinkish-white suspension.

4. CLINICAL INFORMATION

4.1 | Target species

Sheep and cattle

4.2 | Indications for use for each target species

Sheep:
For active immunisation of sheep to reduce the viraemia, mortality and clinical signs caused by the serotype 3 of the bluetongue virus.
Onset of immunity: 3 weeks after completion of the primary vaccination scheme.
Duration of immunity: not established.

Cattle:
For active immunisation of cattle to reduce the viraemia against the serotype 3 of the bluetongue virus.
Onset of immunity: 3 weeks after completion of the primary vaccination scheme.
Duration of immunity: not established.

4.3 | Contraindications

None.

4.4 | Special warnings

Vaccinate healthy animals only.

No information is available on the use of the vaccine in seropositive sheep and cattle, including those with maternal antibodies.

4.5 | Special precautions for use

Special precautions for use in the target species

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment

Not applicable.

4.6 | Adverse events

Sheep:
Very common (>1 animal / 10 animals treated): injection site swelling (painless, diameter up to 4 cm, for up to 9 days, transforms into a nodule); injection site nodule (painless, diameter up to 4 cm, recedes within 14 days).

Common (1 to 10 animals / 100 animals treated): elevated temperature (up to 1 °C, for up to 72 hours).

Very rare (<1 animal / 10,000 animals treated, including isolated reports): loss of appetite; hypersensitivity reaction.

Cattle:
Very common (>1 animal / 10 animals treated): injection site swelling (painless, diameter up to 9 cm, for up to 6 days, transforms into a nodule); injection site nodule (painless, diameter 0.5 to 9 cm, recedes in 25% of animals within 21 days).

Rare (1 to 10 animals / 10,000 animals treated): elevated temperature (up to 1 °C, for up to 24 hours).

Very rare (<1 animal / 10,000 animals treated, including isolated reports): loss of appetite; hypersensitivity reaction.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 | Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy in ewes and cows.

Lactation:
No negative impact on the milk-yield using the vaccine in lactating ewes and cows is expected.

Fertility:
The safety of the vaccines has not been established in breeding males. In this category of animals, the vaccine should be used only according to the benefit-risk assessment by the responsible veterinarian and/or National Competent Authorities on the current vaccination policies against BTV.

4.8 | Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 | Amounts to be administered and administration route

Shake well before use.
Avoid multiple vial broaching.
Avoid introduction of contamination.
Subcutaneous use.

Primary vaccination

Sheep from 2 months of age:
Administer two doses of 2 mL subcutaneously 3 weeks apart.

Cattle from 2 months of age:
Administer two doses of 4 mL subcutaneously 3 weeks apart.

Re-vaccination
Not established.

4.10 | Overdose (symptoms, emergency procedures, antidotes), if necessary

After the administration of a double dose, no adverse reactions other than those described in section “Adverse events” were observed.

4.11 | Withdrawal period(s)

Meat, milk and offal: Zero days.

5. IMMUNOLOGICAL INFORMATION

ATCvet code: QI04AA02.

To stimulate active immunity of sheep and cattle against bluetongue virus serotype 3.

6. PHARMACEUTICAL PARTICULARS

6.1 | Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.2 | Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 10 hours.

6.3 | Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.4 | Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles of 52 mL, 100 mL or 252 mL with bromobutyl stoppers and aluminium seals.

Package sizes:

Cardboard box with 1 bottle containing 52 mL
Cardboard box with 1 bottle containing 100 mL
Cardboard box with 1 bottle containing 252 mL

Not all pack sizes may be marketed.

6.5 | Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.