B. PACKAGE LEAFLET

PACKAGE LEAFLET:

BLUEVAC-4

Suspension for injection for sheep and cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

CZ Veterinaria, S.A.
La Relva s/n – Torneiros
36410 Porriño (España)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC-4, suspension for injection for sheep and cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml of vaccine contains:

Active substance:
Bluetongue virus inactivated,
serotype 4, strain BTV-4/SPA-1/2004 ..... $10^{6.5}$ $CCID_{50}$*

* $CCID_{50}$: 50% cell culture infective dose equivalent to titre prior inactivation (potency confirmed in final batches by challenge in target specie)

Adjuvant:
Aluminium hydroxide ..... 6 mg
Purified saponin (Quil A) ..... 0.05 mg

Excipients:
Thiomersal (preservative) ..... 0.1 mg

4. INDICATIONS

Sheep
Active immunisation of sheep to prevent the viraemia* caused by the serotype 4 of the Bluetongue virus.
*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity:
21 days after completion of the primary vaccination scheme.

Duration of immunity:
1 year after completion of the primary vaccination scheme.

Cattle
Active immunisation of cattle to prevent the viraemia* caused by the serotype 4 of the Bluetongue virus.
*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity:
21 days after completion of the primary vaccination scheme.

Duration of immunity: 1 year after completion of the primary vaccination scheme

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

A transient increase in rectal temperature not exceeding 1ºC is common. It lasts not longer than 24 to 72 hours.

Very common nodules can be observed; in sheep the nodule can reach up to a 3 cm of diameter as maximum (53% of the animals) and decreases progressively throughout 35 days; in cattle, the nodule can reach up to a 5 cm of diameter as maximum and it may persist for undetermined time (even more than 41 days after vaccination in 25% of the animals), and decreases progressively.

Rarely, it can be observed:
- Hipersensitivity reactions (with sialorrhea)
- Systemic signs (lethargy, oedema, malaise, anorexia and death)
- Reproductive disorders (abortion and placental retention)
- Decrease in the production of milk
- Local reactions: pain at the point of injection
- Respiratory signs (dyspnea and nasal discharge)

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep and cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous use

Sheep: Sheep from 2 months of age born to non immunized mothers (or from 2.5 months of age in animals born to immunized sheep): 1 dose of 2 ml administered by subcutaneous injection, independently of weight and age.

Revaccination: 1 dose per year.

Cattle: Cattle from 2 months of age born to non immunized mothers (or from 3 months of age in animals born to immunized calves): 2 doses of 4 ml administered with a 4 weeks interval by subcutaneous injection, independently of weight and age.

Revaccination: 1 dose per year.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use
Maintain usual aseptic conditions

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of the children.
Store and transport refrigerated (2ºC - 8ºC). Protect from light. Do not freeze.
Shelf life after first opening the immediate packaging: 10 hours
Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species

Occasionally, the presence of maternally derived antibodies in ovines of minimum recommended age might interfere with the protection induced by the vaccine.

No information is available on the use of the vaccine in seropositive bovines, including those with maternally derived antibodies.

If used in other domestic and wild ruminant species that are considered at risk of infection, its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of animals prior to mass vaccination. The level of efficacy for other species may differ from that observed in sheep and cattle.

Special precautions for use in animals

Vaccinate healthy animals only

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

Use during pregnancy and lactation

Can be used during pregnancy in ewes and cows

The safety of the veterinary medicinal product has not been established in ewes and cows during lactation.

The safety and efficacy of the veterinary medicinal product has not been established in breeding bovine 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 bluetongue.

Interactions 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.

Overdose (symptoms, emergency procedures, antidotes)

After the administration of a double dose, no adverse reactions other than those described in section 6 were observed.

Incompatibilities

Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pharmacotherapeutic group: Vaccine against Bluetongue virus.
ATCvet codes: sheep QI04AA02; cattle: QI02AA08.

To stimulate active immunity against bluetongue virus, serotype 4.

Reg. No.: 1704 ESP

Formats:
Cardboard box with 1 bottle of 50 mL
Cardboard box with 1 bottle of 100 mL
Cardboard box with 1 bottle of 250 mL

Not all pack sizes may be marketed.

Veterinary use. Medicine subject to veterinary prescription
Administration under control or supervision of a veterinary surgeon