[Version 8.1, 01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BLUEVAC-4

Suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection
White or pinkish-white

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only

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.

4.5 Special precautions for use

Special precautions for use in animals

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

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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

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

Subcutaneous use
Shake well before use
Maintain usual aseptic conditions.

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

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 4.6 were observed.

4.11 Withdrawal period

Zero days

5. IMMUNOLOGICAL PROPERTIES

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

To stimulate active immunity against bluetongue virus, serotype 4.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Purified saponin (Quil A)
Thiomersal
Potassium dihydrogen phosphate
Disodium phosphate anhydrous
Sodium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 10 hours

6.4 Special precautions for storage

Store and transport refrigerated (2ºC - 8ºC). Protect from light . Do not freeze.

6.5 Nature and composition of immediate packaging

Presentation:
50 ml high-density polyethylene bottles with butyl rubber stopper and aluminium seal.
100 ml high-density polyethylene bottles with butyl rubber stopper and aluminium seal.
250 ml high-density polyethylene bottles with butyl rubber stopper and aluminium seal.

Package size:
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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

1704 ESP

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of the first authorisation: 31 October 2006

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Conditions of prescription: **Medical product subject to veterinary prescription.**

Conditions of administration: **Administration under control or supervision of a veterinary surgeon.**