**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine Suspension for injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

| **Active substance:** | **Amount per 2ml dose (for cattle)** | **Amount per 1 ml dose (for sheep)** |
|---|---|---|
| *Clostridium chauvoei* whole culture, inactivated | Meets Ph. Eur.* | Meets Ph. Eur.* |
| **Adjuvant:** | | |
| Potassium aluminium sulphate | 2.4 - 3.2 mg Aluminium | 1.2 - 1.6 mg Aluminium |

*Challenge test according to Ph. Eur.

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Sodium chloride | |
| Thiomersal | 0.24 – 0.36 mg (per 2 ml dose for cattle)<br>0.12 - 0.18 mg (per 1 ml dose for sheep) |
| Formaldehyde | ≤1 mg (per 2 ml dose for cattle)<br>≤0.5 mg (per 1 ml dose for sheep) |

Suspension for injection.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle from 2 weeks of age.
Sheep from 2 weeks of age.

### 3.2 Indications for use for each target species

Active immunisation of cattle or sheep to reduce clostridial disease caused by *C. chauvoei*.

Onset of immunity: 2 weeks after the primary course.

Duration of immunity: 1 year after the primary course (based on serological data).

Passive immunisation of calves and lambs via colostrum from vaccinated dams to reduce clostridial diseases caused by *C. chauvoei*. Passive immunity has been claimed on the basis of antibody responses.
Lambs: The duration of passive immunity is 2 weeks.
Calves: The duration of passive immunity is 8 weeks

### 3.3 Contraindications

None.

### 3.4 Special warnings

Vaccinate healthy animals only.

The effectiveness of the vaccine in providing passive immunity to young lambs and calves depends on these animals ingesting adequate amounts of colostrum on the first day of life.

Reduced efficacy against *C. chauvoei* occur in calves vaccinated at 2 weeks of age.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.

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.

### 3.6 Adverse events

Cattle and sheep

| | |
|---|---|
| Very common<br>(>1 animal / 10 animals treated): | injection site swelling[1]<br>injection site pain[2]<br>injection site abscess<br>injection site skin discolouration[3]<br>injection site reaction NOS[4] |

[1] Swelling may reach up to 6 cm in sheep and 14 cm diameter in cattle. Most local reactions resolve within 3 - 6 weeks in sheep and in less than 10 weeks in cattle
[2] Localised pain for 1-2 days post first vaccination may occur
[3] Skin discolouration returns to normal as the local reaction resolved
[4] Vaccination may give rise to reactions in the underlying tissues at the injection site

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 the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy. The vaccine has been shown to be safe and efficacious in sheep and cattle between 8 and 2 weeks prior to parturition. In the absence of specific data, no recommendation can be made for use of the vaccine during the first or second trimester of pregnancy.
Avoid stress in pregnant ewes and cows.
The use is not recommended during lactation.

### 3.8 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.

### 3.9 Administration routes and dosage

Dose:
Primary vaccination:
*Cattle*: two doses of 2 ml administered six weeks apart.
*Sheep*: two doses of 1 ml administered six weeks apart.
Revaccination:
Revaccination is required every 12 months.

Administration:
By subcutaneous injection preferably in the loose skin on the side of the neck, observing aseptic precautions.
Shake thoroughly before use.
Syringes and needles should be sterilised before use and the injection should be made through an area of clean, dry skin, taking aseptic precautions against contamination.

Vaccination programme*:*
*Sheep and lambs*: The vaccine course should be completed at least two weeks before maximum immunity is required. This may be either a period of risk or in pregnant ewes before lambing.

*Use during pregnancy:* For passive protection of lambs, previously vaccinated pregnant sheep should be vaccinated with one dose (1 ml) of vaccine during the period 2-6 weeks before lambing.

*Lambs*: Lambs born from unvaccinated ewes may be given their first dose of Blackleg from 2 weeks of age.

*Cattle*: The vaccine course should be completed at least two weeks before maximum immunity is required. This may be either a period of risk or in pregnant cattle before calving.

*Use during pregnancy:* For passive protection of calves, previously vaccinated pregnant cattle should be vaccinated with one dose (2 ml) of vaccine during the period 2-8 weeks before calving.

*Calves:* For an optimum immune response, calves from cows vaccinated during pregnancy should not be vaccinated until 8 weeks of age.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

A temporary swelling may occur at the injection site following administration of an overdose. There is no specific antidote.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

### 3.12 Withdrawal periods

Zero days.

## 4. IMMUNOLOGICAL INFORMATION

### 4.1 ATCvet code: QI02AB01 and QI04AB01

To stimulate active immunity in cattle and sheep against *C. chauvoei* and provide passive immunity via the colostrum in young lambs and calves.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 8 hours.

### 5.3 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).
Protect from light.
Do not freeze.

### 5.4 Nature and composition of immediate packaging

Cardboard box with 50 ml high density polyethylene (HDPE) bottle and closed with a chlorobutyl (type 1) rubber bung held in place with an aluminium seal.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products 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 products concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/002/001

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 14 January 2005

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

January 2023

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARDBOARD BOX**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine Suspension for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

| | **Amount per 2ml dose (for cattle)** | **Amount per 1 ml dose (for sheep)** |
|---|---|---|
| *C. chauvoei* whole culture, inactivated | Meets Ph. Eur.* | Meets Ph. Eur.* |

*Challenge test according to Ph. Eur.

## 3. PACKAGE SIZE

50 ml

## 4. TARGET SPECIES

Cattle and Sheep

## 5. INDICATIONS

Active immunisation of cattle or sheep to reduce clostridial disease caused by *C. chauvoei*.

Onset of immunity: 2 weeks after the primary course.

Duration of immunity: 1 year after the primary course (based on serological data).

Passive immunisation of calves and lambs via colostrum from vaccinated dams to reduce clostridial diseases caused by *C. chauvoei*. Passive immunity has been claimed on the basis of antibody responses.
Lambs: The duration of passive immunity is 2 weeks.
Calves: The duration of passive immunity is 8 weeks

## 6. ROUTES OF ADMINISTRATION

Subcutaneous injection.

## 7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 8 hours.

## 9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

## 10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

## 11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

## 14. MARKETING AUTHORISATION NUMBERS

VPA 10387/002/001

## 15. BATCH NUMBER

Lot {number}

LM

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**BOTTLE LABEL**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine Suspension for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

*C. chauvoei* whole culture, inactivated, according to Ph. Eur.

## 3. TARGET SPECIES

Cattle and Sheep

## 4. ROUTES OF ADMINISTRATION

SC
Read the package leaflet before use.

## 5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

## 6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 8 hours.

## 7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Protect from light.
Do not freeze.

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

## 9. BATCH NUMBER

Lot {number}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Blackleg Vaccine Suspension for injection

## 2. Composition

| | Amount per 2 ml dose (for cattle) | Amount per 1 ml dose (for sheep) |
|---|---|---|
| Active substance: *Clostridium chauvoei* whole culture, inactivated | Meets Ph. Eur.* | Meets Ph. Eur.* |
| Adjuvant: Potassium aluminium sulphate | 2.4 - 3.2 mg Aluminium | 1.2 - 1.6 mg Aluminium |
| Excipients: Thiomersal Formaldehyde | 0.24 - 0.36 mg ≤1 mg | 0.12 - 0.18 mg ≤0.5 mg |

* Challenge test according to Ph. Eur.

Suspension for injection.

## 3. Target species

Cattle from 2 weeks of age.
Sheep from 2 weeks of age.

## 4. Indications for use

Active immunisation of cattle or sheep to reduce clostridial disease caused by *C. chauvoei*.

Onset of immunity: 2 weeks after the primary course.

Duration of immunity: 1 year after the primary course (based on serological data).

Passive immunisation of calves and lambs via colostrum from vaccinated dams to reduce clostridial diseases caused by *C. chauvoei*. Passive immunity has been claimed on the basis of antibody responses.
Lambs: The duration of passive immunity is 2 weeks.
Calves: The duration of passive immunity is 8 weeks

## 5. Contraindications

None.

## 6. Special warnings

Special warnings:
Vaccinate healthy animals only.

The effectiveness of the vaccine in providing passive immunity to young lambs and calves depends on these animals ingesting adequate amounts of colostrum on the first day of life.
Reduced efficacy against *C. chauvoei* may occur in calves vaccinated at 2 weeks of age.
Special precautions for safe use in the target species:
In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.

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.

Pregnancy and lactation:
Avoid stress in pregnant ewes and cows at vaccination.
Can be used during pregnancy. The vaccine has been shown to be safe and efficacious in sheep and cattle between 8 and 2 weeks prior to parturition. In the absence of specific data, no recommendation can be made for use of the vaccine during the first or second trimester of pregnancy.
The use is not recommended during lactation.

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.

Overdose:
A temporary swelling may occur at the injection site following administration of an overdose. There is no specific antidote.

Special restrictions for use and special conditions for use:
Prior to first time use on a farm, it is strongly recommended that the advice of a veterinary surgeon is sought.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

## 7. Adverse events

Cattle and sheep

| | |
|---|---|
| Very common<br>(>1 animal / 10 animals treated): | injection site swelling[1]<br>injection site pain[2]<br>injection site abscess<br>injection site skin discolouration[3]<br>injection site reaction NOS[4] |

[1] Swelling may reach up to 6 cm in sheep and 14 cm diameter in cattle. Most local reactions resolve within 3 - 6 weeks in sheep and in less than 10 weeks in cattle
[2] Localised pain for 1-2 days post first vaccination may occur

[3] Skin discolouration returns to normal as the local reaction resolved
[4] Vaccination may give rise to reactions in the underlying tissues at the injection site

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

## 8. Dosage for each species, routes and method of administration

***Dose:***
Primary vaccination:
Cattle: two doses of 2 ml administered six weeks apart.
Sheep: two doses of 1 ml administered six weeks apart.
Revaccination:
Revaccination is required every 12 months.

***Administration:***
By subcutaneous injection preferably in the loose skin on the side of the neck, observing aseptic precautions.

***Vaccination programme:***
*Sheep and lambs:* The vaccine course should be completed at least two weeks before maximum immunity is required. This may be either a period of risk or in pregnant ewes before lambing.

***Use during pregnancy:***
For passive protection of lambs, previously vaccinated pregnant sheep should be vaccinated with one dose (1 ml) of vaccine during the period 2-6 weeks before lambing.

***Lambs***: Lambs born from unvaccinated ewes may be given their first dose of Blackleg from 2 weeks of age.

***Cattle****:* The vaccine course should be completed at least two weeks before maximum immunity is required. This may be either a period of risk or in pregnant cattle before calving.

***Use during pregnancy:***
For passive protection of calves, previously vaccinated pregnant cattle should be vaccinated with one dose (2 ml) of vaccine during the period 2-8 weeks before calving.

***Calves****:* For an optimum immune response, calves from cows vaccinated during pregnancy should not be vaccinated until 8 weeks of age.

## 9. Advice on correct administration

Administer by subcutaneous injection preferably in the loose skin on the side of the neck, observing aseptic precautions. The container should be well shaken before doses are withdrawn.
Syringes and needles should be sterilised before use and the injection should be made through an area of clean, dry skin taking precautions against contamination.

In any animal population, there may be a number of individuals which fail to respond fully to vaccination.

Successful vaccination depends upon the correct storage and administration of the vaccine together

with the animal's ability to respond. This can be influenced by such factors as genetic constitution, intercurrent infection, age, the presence of maternally derived antibodies, nutritional status, concurrent drug therapy and stress.

## 10. Withdrawal periods

Zero days.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C - 8 °C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after expiry date which is stated on the label/carton.

Shelf life after first opening the immediate packaging: 8 hours

## 12. Special precautions for disposal

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 applicable national collection systems.

Ask your veterinary surgeon how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

VPA 10387/002/001

50 ml flexible packs.

## 15. Date on which the package leaflet was last revised

01/2023

Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park,
Loughlinstown
Co. Dublin
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

Manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

## 17. Other information

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