

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton
50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:	Amount per 2 ml dose (for cattle)	Amount per 1 ml (for sheep)
<i>Clostridium chauvoei</i> 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

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

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

Vm 60021/3004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING

UNITS

Vial label

50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Contains *Clostridium chauvoei* whole culture, inactivated according to Ph. Eur.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 8 hours.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Blackleg Vaccine suspension for injection

2. Composition

Each dose contains:

Active substance:	Amount per 2 ml dose (for cattle)	Amount per 1 ml (for sheep)
<i>Clostridium chauvoei</i> 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	0.24 – 0.36 mg	0.12 – 0.18 mg
Formaldehyde	≤ 1.0 mg	≤ 0.5 mg

*Challenge test according to Ph. Eur.

Whitish suspension.

3. Target species

Cattle and sheep.

4. Indications for use

For the active immunisation of sheep and cattle against disease associated with infections caused by *Clostridium chauvoei* (Blackleg and post-parturient gangrene).

Onset and duration of immunity have not been established.

5. Contraindications

Not for use in ewes producing milk for human consumption.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

Clinical trials have demonstrated that the presence of maternal antibodies against *C. chauvoei* may reduce the antibody response to vaccination in young lambs.

Therefore, to ensure an optimal response in young animals with high levels of MDA, the primary vaccination should be delayed until the levels wane (which is after about 8-12 weeks of age).

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 veterinary medicinal product 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.

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.

Pregnancy:

The use is not recommended during the first or second trimester of pregnancy. The veterinary medicinal product has been shown to be safe and efficacious in sheep and cattle between 8 and 2 weeks prior to parturition. Avoid stress in pregnant ewes and cows at vaccination.

Interaction with other medicinal products and other forms of interaction:

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

Overdose:

In calves and lambs, local reactions may increase slightly if twice the recommended dose is administered.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle and sheep:

Very common (>1 animal / 10 animals treated):	Injection site swelling ¹ , injection site pain ² , injection site abscess Injection site skin discolouration ³ Injection site reaction NOS ⁴
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction ⁵

¹ In some cases, up to 14 cm diameter. Most local reactions resolve in less than 10 weeks.

² Occurring for 1-2 days post vaccination.

³ Returns to normal as the local reaction is resolved.

⁴ Vaccination may give rise to reactions in the underlying tissues at the injection site.

⁵ Appropriate dose of adrenaline and/or antihistamines should be administered without delay.

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 the 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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Subcutaneous use preferably in the loose skin on the side of the neck.

Dose:

Primary vaccination:

Cattle: two doses of 2 ml administered 6 weeks apart, 2-3 weeks before the expected period of risk.

Sheep: two doses of 1 ml administered 6 weeks apart, 2-3 weeks before the expected period of risk.

Revaccination:

Revaccination with a single dose is advised annually before the expected period of risk.

9. Advice on correct administration

Shake well 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.

10. Withdrawal periods

Cattle and sheep: Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C - 8 °C)

Do not freeze.

Protect from light.

Once opened use within 8 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

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. These measures should help protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 60021/3004

Cardboard box with 1 bottle of 50 ml closed with a rubber stopper and aluminium seal.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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
Dublin 18
D18 T3Y1
Ireland
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

POM- VPS

Gavin Hall
Approved: 19 December 2025