SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:	**Amount per 2 ml 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**
Thiomersal	0.24 – 0.36 mg (per 2 ml dose for cattle) 0.12 – 0.18 mg (per 1 ml dose for sheep)
Formaldehyde	≤ 1.0 mg (per 2 ml dose for cattle) ≤ 0.5 mg (per 1 ml dose for sheep)
Sodium chloride	

Whitish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

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.

3.3 Contraindications

Not for use in ewes producing milk for human consumption.
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3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.

3.9 Administration routes and dosage

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

Dose:
Primary vaccination:

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

Sheep: two doses of 1 ml administered six 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.
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.

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

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

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

Cattle and sheep: Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AB01 and QI04AB01

To stimulate active immunity against *Clostridium chauvoei* in cattle and sheep.

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 package: 8 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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

5.5 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5157

8. DATE OF FIRST AUTHORISATION

19 October 2005

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

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 19 December 2025