SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep

4.2 Indications for use, specifying the 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 determined for this vaccine.

4.3 Contraindications

None

4.4 Special warnings for each 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 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.

4.5 Special precautions for use

i. Special precautions for use in animals

In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.
Do not vaccinate sick or immunodeficient animals.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental self-injection, encourage bleeding and wash the area immediately with water. If a local reaction develops, seek medical advice showing the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency & seriousness)

Occasional hypersensitivity reactions may occur. In such cases an appropriate dose of adrenalin and/or antihistamines should be administered without delay.
Most vaccinated animals may experience reactions to vaccination. These reactions are usually localised swelling or induration at the injection site but may also include abscess or other reaction in the underlying tissues at the injection site.
Swelling at the injection site occurs in the majority of animals and may reach 14 cm diameter. Most local reactions resolve in less then 10 weeks. In up to 17% of animals an abscess may develop. Vaccination may give rise to reactions in the underlying tissues at the injection site.
Skin discolouration (which returns to normal as the local reaction resolved) and localised pain for 1-2 days post first vaccination may occur at the injection site.
The local reactions do not affect the general health, demeanour, feeding or weight gain of the animals.

4.7 Use during pregnancy, lactation or lay

No side effects other than those described under 4.6 are expected when the vaccine is used 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 third of pregnancy.
Avoid stress in pregnant ewes and cows.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of the concurrent use of this vaccine with any other. 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

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

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period

Cattle and sheep - Zero days.

5. IMMUNOLOGICAL PROPERTIES

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

ATCvet codes: QI02AB01 and QI04AB01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium aluminium sulphate
Thiomersal
Formaldehyde
Sodium chloride

6.2 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: 3 years.
Shelf-life after first opening the immediate package: 8 hours.

6.4 Special precautions for storage

Store and transport between +2°C and +8°C. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 bottle of 50 ml high density polyethylene (HDPE) bottle closed with pharmaceutical grade rubber stopper and aluminium seal.

6.6 Special precautions for the disposal of unused veterinary 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

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co. Dublin
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 60021/3004

9. DATE OF FIRST AUTHORISATION

19 October 2005

10. DATE OF REVISION OF THE TEXT

November 2024

Gavin Hall

Approved 25 November 2024