PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Blackleg Vaccine – Carton
50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active ingredient:	**Amount per 2ml dose (for cattle)**	**Amount per 1ml (for sheep)**
C. 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	0.24 – 0.36 mg	0.12 – 0.18 mg

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Clostridial vaccine for cattle and sheep

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose:
Cattle – 2 x 2 ml, 6 weeks apart

Sheep – 2 x 1 ml, 6 weeks apart

For subcutaneous injection.
Shake thoroughly before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Do not mix with any other veterinary medicinal product.
For further information on Uses, Dosage, Contraindications and warnings, see package leaflet.

10. EXPIRY DATE

Exp:
Opened containers should be discarded within 8 hours of opening.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-VPS
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4010

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blackleg Vaccine – vial label
50ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine
Suspension for injection
Clostridial vaccine for cattle and sheep.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains *C. chauvoei* whole culture according to Ph. Eur.
Preservative: Thiomersal

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Shake thoroughly before use.
For subcutaneous injection.

5. WITHDRAWAL PERIOD

Withdrawal period – zero days

6. BATCH NUMBER

Lot No

7. EXPIRY DATE

EXP:
Opened containers should be discarded within 8 hours of opening.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Read the package leaflet before use.
Store and transport between +2°C and +8°C
Protect from light.
Do not freeze.
Keep the container in the outer carton.
Do not mix with any other veterinary medicinal product.
Keep out of reach and sight of children.
For animal treatment only.
Vm 42058/4010
POM-VPS
To be supplied only on veterinary prescription.

MA Holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

PACKAGE LEAFLET FOR:
Blackleg Vaccine

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine,
Suspension for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Suspension for injection containing:

Active ingredient:	**Amount per 2ml dose (for cattle)**	**Amount per 1ml (for sheep)**
***C. 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	0.24 – 0.36 mg	0.12 – 0.18 mg

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

Side effects: 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.
The local reactions do not affect the general health, demeanour, feeding or weight gain of the animals.
Swelling at the injection site occurs in the majority of animals and may reach 14 cm diameter. Most local reactions resolve in less than 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.

7. TARGET SPECIES

Cattle and Sheep

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 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.

9. ADVICE ON CORRECT ADMINISTRATION

The container should be 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 aseptic precautions against contamination.
Avoid the introduction of contamination during use.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport between +2°C and +8°C
Protect from light.

Do not freeze.
Opened containers should be discarded within 8 hours of opening.
Keep out of reach and sight of children.
For animal treatment only.

12. SPECIAL WARNING(S)

Warnings: Avoid stress in pregnant ewes and cows at vaccination. 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.
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 the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.
In calves and lambs, local reactions may increase slightly if twice the recommended dose is administered.
Do not vaccinate sick or immunodeficient animals.
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.
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.
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused product or waste material should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

50 ml flexible packs.
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.

Legal category POM-VPS

To be supplied only on veterinary prescription.

Marketing authorisation number Vm 42058/4010

Approved 19 August 2020