PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Suspension for injection containing per dose (2ml) five strains of Clostridium chauvoei, cells and equivalent toxoid inducing ≥ 0.5 guinea pig PD_{90}. Also contains Aluminium hydroxide as an adjuvant and 0.26 mg/dose Thiomersal as preservative.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50ml (25 x 2ml doses)

5. TARGET SPECIES

In Cattle and sheep

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: Cattle and sheep 2ml by subcutaneous injection.

NON-COLLAPSIBLE BOTTLE
Vaccinator with vented draw-off spike or similar device must be used.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero Days

9. SPECIAL WARNING(S), IF NECESSARY

For further details of USES, DOSAGE, ADMINISTRATION, CONTRA-INDICATIONS, DISPOSAL ADVICE and WARNINGS, see package leaflet.

10. EXPIRY DATE

Batch/Expiry end of:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C - 8 °C).
In-use shelf life : 10 hours
Do not freeze.
Keep the container in the outer carton.

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

For further details of USES, DOSAGE, ADMINISTRATION, CONTRA-INDICATIONS, DISPOSAL ADVICE and WARNINGS, see package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription

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

KEEP OUT OF REACH AND SIGHT OF CHILDREN**.**

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Bucks, MK7 7AJ

Distributed in Northern Ireland by:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4507

17. MANUFACTURER'S BATCH NUMBER

Batch/Expiry end of:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Five strains of Clostridium chauvoei, cells and equivalent toxoid inducing ≥ 0.5 guinea pig PD_{90}. Also contains Aluminium hydroxide and Thiomersal.

3. PHARMACEUTICAL FORM

Suspension for s.c.injection

4. PACKAGE SIZE

50ml (25 x 2ml doses)

5. TARGET SPECIES

in Cattle and sheep

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: Cattle and sheep 2ml by subcutaneous injection.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero Days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Batch/Expiry end of:

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

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

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4507

17. MANUFACTURER'S BATCH NUMBER

Batch/Expiry end of:

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:
Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Bucks, MK7 7AJ

Manufacturer
Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Bucks, MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine

Suspension for injection in cattle and sheep

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

Suspension for injection containing five strains of Clostridium chauvoei, cells and equivalent toxoid inducing $\geq$ 0.5 guinea pig PD_{90}.

Also contains Aluminium hydroxide as an adjuvant and
0.26 mg/dose Thiomersal as preservative.

4. INDICATION(S)

To stimulate active immunity against Blackleg (*Clostridium chauvoei* infection) in cattle and sheep.

Significant levels of immunity cannot be expected until two weeks after the second dose of vaccine in the primary vaccination course. From experience from field use, the duration of active immunity is expected to last one year. The duration of passive immunity is at least 4 - 6 weeks in lambs provided that lambs receive adequate quantities of colostrum in the first 12 hours after birth.

5. CONTRAINDICATIONS

Occasional hypersensitivity may occur.

6. ADVERSE REACTIONS

In section: Contra-indications, warnings, etc.

Occasional hypersensitivity may occur.
Vaccination may result in small (< 10 cm) transient injection site reactions possibly lasting for up to 3 - 4 months after vaccination.
Local tissue irritating effects of alhydrogel-adjuvanted vaccines reveal granulomatous inflammatory reactions consisting mainly of activated macrophages containing foamy cytoplasm, epithelioid cells, small lymphocytes and multinuclear giant cells.

Reactions similar to those described above were observed following administration of a double dose.

7. TARGET SPECIES

Cattle and sheep

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

When starting a Blackleg vaccination programme, two doses of vaccine must be given thereafter, a single booster dose is required annually.

The vaccine should be administered by subcutaneous injection in the lateral side of the upper neck observing aseptic precautions.

Cattle and sheep: 2 ml/dose

Cattle

Two injections separated by an interval of 3 - 4 weeks to animals from 3 months of age onwards.

Immunisation to be completed 2 - 3 weeks before period of risk. Revaccination with a single booster injection 2 - 3 weeks before period of risk. The interval for booster injections should be not more than 12 months.

Sheep

Two injections should be given, preferably separated by an interval of at least 6 weeks with the second vaccination being given 3 - 4 weeks before lambing. Subsequent pregnancies: a single booster injection 3 - 4 weeks before lambing. Ewes can be vaccinated in late pregnancy.

Lambs may be vaccinated from 3 weeks of age onwards. Two injections with an interval of 3-4 weeks to be completed 2 - 3 weeks before period of risk.

The vaccine bottle must be shaken well before use.

9. ADVICE ON CORRECT ADMINISTRATION

Syringes and needles must be from gamma irradiated packs or freshly sterilised by boiling for at least 20 minutes. No alcohol or other disinfectants should be used for sterilisation.

The use of an automatic vaccinator is recommended. Since the bottle is non-collapsible, a vaccinator with a vented draw-off spike or similar device must be used. The instructions supplied with such equipment should be noted and care should be taken to ensure the delivery of the full dose, particularly with the final few doses from the bottle.

10. WITHDRAWAL PERIOD(S)

Zero Days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.
Store in a refrigerator (+2°C to +8°C). Do not freeze.
Keep the container in the outer carton.
Shelf-life after first opening the container: 10 hours

12. SPECIAL WARNING(S)

In section: Contra-indications, warnings, etc.

In any group of animals, a small number of individuals may fail to respond to vaccination as a result of immunological incompetence. Satisfactory immune responses will only be attained in healthy animals, thus it is important to avoid vaccination of animals which have an intercurrent infection or metabolic disorders. When handling animals stress should be avoided, particularly during the later stages of pregnancy when there is a risk of inducing abortion and metabolic disorders.

The nutritional and metabolic status of pregnant ewes is extremely important at the time of vaccination. If in doubt, advice should be sought from a veterinary surgeon.

No information is available on the efficacy of the vaccine in young animals with maternally derived antibodies.

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

Do not mix with any other veterinary medicinal product

Operator Warnings
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2012

15. OTHER INFORMATION

For animal treatment only.

LEGAL CATEGORY: POM-VPS

To be supplied only on veterinary prescription.

Pack sizes

Carton containing a 50 ml polyethylene multidose bottle, closed with a closed with a combination seal.

MA number : Vm 01708/4507

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

Approved: 21/07/2017