SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Blackleg Vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):	per ml
Five strains of *Clostridium chauvoei* cells and equivalent toxoid	inducing ≥ 0.5 guinea pig PD_{90}
Adjuvant(s):	
Aluminium hydroxide gel	200 mg
Excipients:	
Thiomersal (preservative)	0.13 mg

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 active immunisation of cattle and sheep against Blackleg.

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

i. Special precautions for use in animals

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 disorder.
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.

ii. Special precautions to be taken by the person administering the 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Ewes can be vaccinated during late pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

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.
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.

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.

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

Reactions similar to those described in section 4.6 were observed following administration of a double dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code:
Sheep: QI04AB01
Cattle: QI02AB01
To stimulate active immunity against Blackleg (*Clostridium chauvoei* infection).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maleic acid
Tris
Sodium chloride
Formaldehyde
Thiomersal
Water for injections

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 container: 10 hours

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard box containing a 50 ml polyethylene multidose bottle closed with a closed with a rubber disc/stopper and an aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4507

9. DATE OF RENEWAL OF AUTHORISATION

20 April 2010

10. DATE OF REVISION OF THE TEXT

January 2012