SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Huskvac

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (25 ml) contains:
Active substance:
Dictyocaulus viviparus 3rd stage irradiated larvae: ≥ 1000 viable larvae
≤ 2000 viable larvae

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the active immunisation of cattle to reduce clinical signs and lesions of parasitic bronchitis attributable to *Dictyocaulus viviparous* (lungworm).

Onset of immunity: 2 weeks after completion of the basic vaccination scheme.

Duration of immunity: lungworm immunity is maintained from season to season by the exposure to lungworm larvae, which in most cases occurs from the grazing of normal pastures. If such exposure does not occur, a single booster dose is required prior to each season's turnout.

4.3 Contraindications

Do not use in calves showing any signs of illness, particularly those exhibiting any signs of respiratory distress.

4.4 Special warnings for each target species

Routine vaccination of housed or suckled young stock prior to exposure to field lungworm challenge will help protect the calves and help reduce the levels of pasture contamination with lungworm larvae. However, owing to the ability of

lungworm larvae to survive on pasture, calfhood vaccination programmes to control lungworm infection can only be successful if all susceptible calves are vaccinated in the spring before exposure to natural field infection occurs at turnout or weaning.
A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system.

Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration. Immuno-competence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

4.5 Special precautions for use

i) Special precautions for use in animals

Vaccinate only healthy animals.
Following vaccination, vaccinated stock should not be mixed with unvaccinated stock or allowed to graze on pastures recently used by unvaccinated stock until 2 weeks after the second dose of Bovilis Huskvac.

Note: For optimum benefit it is important that the calf is exposed to pasture carrying some infection after this time, as this low level exposure enhances the immunity induced by vaccination with Bovilis Huskvac.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Transient episodes of coughing may occur approximately 7 days after either dose of Bovilis Huskvac but these usually subside in a few days.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during 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 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.

To ensure residual effects of long-acting anthelmintics and endectocides or sustained release bolus preparations do not interfere with the development of immunity following lungworm vaccination, avoid vaccination during period of their activity, and do not use until 14 days after the second dose of Bovilis Huskvac.

4.9 Amounts to be administered and administration route

Vaccinate healthy animals of 8 weeks of age and older.
Shake bottle well immediately before use and administer the full dose (25 ml) orally.

Vaccination regime
Basic vaccination scheme
Two doses at a dosage interval of approximately 4 weeks.

Re-vaccination
Lungworm immunity is maintained from season to season by the exposure to lungworm larvae, which in most cases occurs from the grazing of normal pastures after vaccination. Under these conditions of exposure, re-vaccination is generally not required.

A single dose of Bovilis Huskvac prior to each season's turnout will boost immunity where such exposure has not occurred, e.g. extensive use of anthelmintics or if using reserved or clean pasture for a large part of the grazing season.

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

No symptoms other than those detailed in section 4.6 were observed following administration of twice the recommended dose.

4.11 Withdrawal Period

Zero days.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for bovidae, Cattle, Live parasitic vaccines;
ATC Vet Code: QI02AN01.
The vaccine contains third stage larvae of *D. viviparus* irradiated to prevent further development, and stimulates active immunity against *D. viviparus* infection.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium chloride
Sodium Phosphate, Dibasic, anhydrous
Monobasic Potassium Phosphate
Purified Water

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: 90 days.

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

25 ml larval suspension in 30 ml glass hydrolytic class type III bottles, closed with a metal screwcap with a PEP faced inlay.
Cardboard box containing 12 x 25 ml (1 dose) bottles.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4137

9. DATE OF THE FIRST AUTHORISATION

23 September 2005

10. DATE OF REVISION OF THE TEXT

January 2025

Gavin Hall
Approved: 13 January 2025