

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Huskvac oral suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 25 ml dose contains:

Active substances:

Dictyocaulus viviparus 3rd stage irradiated larvae: ≥ 1000 viable larvae
 ≤ 2000 viable larvae

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Potassium chloride
Sodium phosphate, dibasic, anhydrous
Monobasic potassium phosphate
Purified water

Clear aqueous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

Vaccinate healthy animals only.

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, calfhod 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 this vaccine.

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 this vaccine.

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

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Cough ¹ .
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¹ May occur approximately 7 days after either dose. Transient episodes, which usually subside in a few days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

3.8 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 the period of their activity, and do not use these veterinary medicinal products until 14 days after the second dose of this vaccine.

3.9 Administration routes and dosage

Oral use.

One dose: 25 ml.

Vaccinate healthy animals of 8 weeks of age and older.

Shake bottle well immediately before use.

Vaccination regime

Basic vaccination scheme

Two doses at a dosage interval of approximately 4 weeks.

Revaccination

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, revaccination is generally not required.

A single dose of this vaccine 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No symptoms other than those detailed in section 3.6 were observed following administration of twice the recommended dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AN01.

The vaccine contains third stage larvae of *D. viviparus* irradiated to prevent further development and stimulates active immunity against *D. viviparus* infection.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 90 days.

5.3 Special precautions for storage

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

5.4 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.

Pack size:

Cardboard box containing 12 x 25 ml (1 dose) bottles.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/081/001

8. DATE OF FIRST AUTHORISATION

22/12/2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

18/08/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).