PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Outer Carton (12 x 25 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Huskvac

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (25 ml) contains: 1000 - 2000 viable 3rd stage irradiated *Dictyocaulus viviparus* larvae.

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

12 doses
(12 x 25 ml)

5. TARGET SPECIES

Target species: Cattle.

6. INDICATION(S)

Oral lungworm vaccine.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.
Shake well before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Following text included in red/white circle on front panel

Notice:
Short Shelf Life Vaccine
Store between +2 °C and +8 °C at all times
DO NOT FREEZE
PLEASE CHECK EXPIRY DATE BEFORE USE

10. EXPIRY DATE

EXP end of: {month/year}.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Keep the container in the outer carton.

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

Disposal: read 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-V
To be supplied only on veterinary. prescription.

IE only
POM (E)
Prescription Only Medicine (Exempt)

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder in the UK:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

MA holder in Ireland and distributor in Northern Ireland:

Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road
Dublin 24, Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4328

IE only
VPA 10996/081/001

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Glass Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Huskvac
Oral suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (25 ml) contains 1000 - 2000 viable 3rd stage irradiated *Dictyocaulus viviparus* larvae.

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

1 dose (25 ml)

4. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP end of:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Keep the container in the outer carton.

UK only
Vm 01708/4328
POM-V
MSD Animal Health UK Ltd.

IE only
VPA 10996/081/001
Intervet Ireland Ltd.

PACKAGE LEAFLET FOR:

Bovilis Huskvac

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

Marketing authorisation holder:

UK only
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

IE only
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24, Ireland

Manufacturer responsible for batch release:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Bucks, MK7 7AJ, UK
Or
Intervet International B.V.
Wim de Korverstraat 35
5831 AN Boxmeer
The Netherlands

The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Huskvac
Oral suspension.

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

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

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Transient episodes of coughing may occur approximately 7 days after either dose of Bovilis Huskvac but these usually subside in a few days.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

See above.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C - 8 °C).
Do not freeze.

12. SPECIAL WARNING(S)

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.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.

Pregnancy:
Can be used during pregnancy.

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 Bovilis Huskvac.

Overdose (symptoms, emergency procedures, antidotes):
No symptoms other than those detailed in the section 'Adverse Reactions' were observed following administration of twice the recommended dose.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION>

For animal treatment only.
Pack size: Carton with 12 x 25 ml (1 dose) bottles.

UK only
Vm 01708/4328
POM-V
To be supplied only on veterinary prescription.

IE only
VPA 10996/081/001
POM(E)
Prescription Only Medicine (Exempt).

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