PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR marker inac suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml: 60 ELISA units inactivated BHV-1 (gE^-).
Aluminium salts, formaldehyde.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 ml (5 doses)
20 ml (10 doses)
50 ml (25 doses)
100 ml (50 doses)
200 ml (100 doses)
10 x 10 ml (5 doses)
10 x 20 ml (10 doses)
10 x 50 ml (25 doses)
10 x 100 ml (50 doses)
10 x 200 ml (100 doses)

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 8 - 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.

12. SPECIAL 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

For animal treatment only. To be supplied only on veterinary prescription.

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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/3039

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label of glass or plastic vial: 100 ml and 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR marker inac suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml: 60 ELISA units inactivated BHV-1 (gE^-).
Aluminium salts, formaldehyde.

3. PHARMACEUTICAL FORM

Suspension for injection.

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

100 ml (50 doses)
200 ml (100 doses)

5. TARGET SPECIES

Cattle

6. INDICATION

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 8 - 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.

12. SPECIAL 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

For animal treatment only.

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

15. MARKETING AUTHORISATION NUMBER

Vm 01708/3039

16. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of glass or plastic vial: 10 ml, 20 ml and 50 ml

Cattle pictogram

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR marker inac

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inac BHV-1 (gE^-): 60 ELISA units per dose (2 ml)

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

10 ml (5 doses)
20 ml (10 doses)
50 ml (25 doses))

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 8 - 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

Bovilis IBR marker inac suspension for injection for cattle

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

Marketing authorization holder:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR marker inac suspension for injection for cattle

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

Each dose of 2 ml contains:
Inactivated bovine herpesvirus type 1 (BHV-1) strain GK/D (gE^-)*: 60 ELISA units**
Aluminium-phosphate and -hydroxide (Al^{3+}): 6.0 - 8.8 mg
Formaldehyde: 0.6 - 1.0 mg

* gE^-: glycoprotein E negative
** inducing 6.1 - 11.1 log_2 virus neutralising units in the mouse potency test.

Pink turbid suspension.

4. INDICATION(S)

For active immunisation of cattle to reduce the intensity and duration of clinical signs (pyrexia) induced by an infection with bovine herpesvirus type 1 (BHV-1) as well as to reduce the replication and nasal excretion of the field virus.

Onset of immunity: - 3 weeks
Duration of immunity:- 6 months
The schedule using Bovilis IBR marker live for primary vaccination and revaccination after 6 months with Bovilis IBR marker inac, will result in protective immunity that lasts for 12 months.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A local reaction at the injection site may occur in very rare cases.
Hypersensitivity reactions can occur in very rare cases. In such cases an appropriate symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

2 ml per animal, intramuscular injection.

All cattle can be vaccinated from an age of three months onwards.

Primary vaccination:
Two vaccinations with an interval of 4 weeks.

Re-vaccination:
One vaccination every 6 months.

Bovilis IBR marker inac can be used for re-vaccination in a schedule where Bovilis IBR marker live has been used for primary vaccination:

Primary vaccination:
Consult the product literature for Bovilis IBR marker live for advice.

First re-vaccination:
A single vaccination should be given 6 months after primary vaccination.

Subsequent re-vaccinations:
Single vaccinations given at intervals no greater than 12 months.

9. ADVICE ON CORRECT ADMINISTRATION

Use sterile vaccination equipment. Before use, allow the vaccine to reach ambient temperature (15 °C -25 °C). Shake well before use.

10. WITHDRAWAL PERIOD

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.
Shelf-life after first opening the immediate packaging: 8 - 10 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Efficacy has not been demonstrated in the face of maternally derived antibodies.

Special precautions for use in animals:
Vaccinate only healthy animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self injection, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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.

Overdose (symptoms, emergency procedures, antidotes):
Administration of a double dose does not cause other effects than after a single dose.

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2020

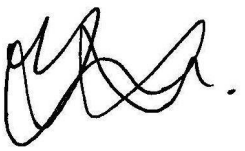
15. OTHER INFORMATION

Bovilis IBR marker inac is an inactivated adjuvanted vaccine for active immunisation of cattle against bovine herpesvirus type 1 (BHV-1). The vaccine does not elicit antibodies to glycoprotein E of BHV-1 (marker vaccine). This enables discrimination between cattle vaccinated with the product and cattle infected with BHV-1 field virus.

Pack sizes:
Cardboard box with 1 glass or plastic vial (5 doses).
Cardboard box with 1 glass or plastic vial (10 doses)
Cardboard box with 1 glass or plastic vial (25 doses)
Cardboard box with 1 glass or plastic vial (50 doses)
Cardboard box with 1 glass or plastic vial (100 doses)
Cardboard box with 10 glass or plastic vials (5 doses)
Cardboard box with 10 glass or plastic vials (10 doses)
Cardboard box with 10 glass or plastic vials (25 doses)
Cardboard box with 10 glass or plastic vials (50 doses)
Cardboard box with 10 glass or plastic vials (100 doses)

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.



Approved: 10 October 2023