ARTICULARS TO APPEAR ON THE OUTER PACKAGE – CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR Marker Inac suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Bovine herpesvirus 1 (BHV-1), strain GK/D gE^-, inactivated: 60 ELISA units.

3. 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)

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 – 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5008
Vm 06376/3008

15. 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

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Bovine herpesvirus 1 BHV-1, strain GK/D gE^-, inactivated: 60 ELISA units.

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

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 – 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS – glass or plastic vial: 10 ml, 20 ml and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR Marker Inac

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

BHV-1, strain GK/D gE^{-}, inactivated: 60 ELISA units per dose (2 ml)

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 – 10 hours.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bovilis IBR Marker Inac suspension for injection for cattle

2. Composition

Each dose (2 ml) contains:

Active substances:
Bovine herpesvirus 1 (BHV-1), strain GK/D gE^-*, inactivated: 60 ELISA units**.
* gE^-: glycoprotein E negative
** inducing 6.1 – 11.1 $\log_2$ virus neutralising units in mouse potency test

Adjuvants:
Aluminium-phosphate and -hydroxide (Al^{3+}): 6.0 – 8.8 mg.

Excipients:
Formaldehyde: 0.6 – 1.0 mg

Pink turbid suspension.

3. Target species

Cattle.

4. Indications for use

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 after completion of the primary vaccination schedule
Duration of immunity: 6 months after vaccination

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. Special warnings

Special warnings:
Vaccinate healthy animals only.
Efficacy has not been demonstrated in the face of maternally derived antibodies.

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 the 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:
At a two-fold overdose, no effects other than those described in section “Adverse events” have been observed.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle:

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Injection site reaction, Hypersensitivity reaction[1].

[1]In such cases an appropriate symptomatic treatment should be administered.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intramuscular use.
Administer one dose (2 ml) per animal.
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 periods

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 8 – 10 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/5008
Vm 06376/3008

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

Local representative:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes, MK7 7AJ, United Kingdom

Contact details to report suspected adverse events:
UK(GB)
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

UK(NI)
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

This product 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.

POM-V

Gavin Hall
Approved: 03 December 2025