PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR Marker Live lyophilisate and solvent for suspension for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose (2 ml):
Live bovine herpesvirus type 1, strain GK/D (gE^-): $10^{5.7}$ - $10^{7.3}$ $TCID_{50}$.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

4. PACKAGE SIZE

5 doses
10 doses
25 doses
50 doses
100 doses
10 x 5 doses
10 x10 doses
10 x 25 doses
10 x 50 doses
10 x 100 doses

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M. / intranasal use.
1 dose of 2 ml.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 3 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

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

Disposal: Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
Subject to medical prescription. (to be replaced by the national symbol / abbreviation / text)

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 01708/3025

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE LABEL

Vial label - Lyophilisate

Company logo and cattle pictogram

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR Marker Live lyophilisate for suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

BHV-1, strain GK/D (gE^-): $10^{5.7}$ - $10^{7.3}$ $TCID_{50}$ per dose (2 ml)

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

5 doses
10 doses
25 doses
50 doses
100 doses

4. ROUTE(S) OF ADMINISTRATION

I.M. / intranasal use.

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 3 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON IMMEDIATE VIAL LABEL OF THE SOLVENT

Label of glass and PET vials - Solvent

1. NAME OF THE SOLVENT

Unisolve
Solvent for Bovilis IBR marker live

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

10 ml
20 ml
50 ml
100 ml
200 ml

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

Store below 25 °C.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

Bovilis IBR marker Live lyophilisate and solvent for suspension for cattle

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

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR marker Live lyophilisate and solvent for suspension for cattle

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

Each dose of 2 ml reconstituted vaccine contains:
Live bovine herpesvirus type 1 (BHV-1), strain GK/D (gE^-)*: $10^{5.7}$ - $10^{7.3}$ $TCID_{50}$**.

* gE^-: glycoprotein E negative
** $TCID_{50}$: tissue culture infective doses 50%

Lyophilisate: off-white to light pink-coloured pellet.
Solvent: colourless solution.

4. INDICATION(S)

Active immunisation of cattle to reduce the intensity and duration of the clinical respiratory signs induced by an infection with BHV-1 and to reduce nasal excretion of field virus.

Onset of immunity:
An increase in immunity was demonstrated 4 days after intranasal vaccination and 14 days after intramuscular vaccination of 3 month old seronegative animals.

Duration of immunity:
After intranasal administration to 2 week old calves immunity lasts at least until the age of 3-4 months. In the presence of maternally derived antibodies, the protection of the vaccine may not be complete until a second vaccination. This second vaccination

should be administered at 3-4 months of age and will result in protective immunity that lasts for at least 6 months.
Single intranasal or intramuscular vaccination of 3 months old animals provides protective immunity (reduction of clinical signs and reduction of viral excretion), which was demonstrated via challenge 3 weeks after vaccination. Reduction of viral excretion is maintained for at least 6 months after single vaccination.
Revaccination to ensure protection after the initial 6 month protection period has elapsed will result in protective immunity that lasts for 12 months.

No information is available on the efficacy of the vaccine to prevent a latent wild virus infection or to prevent wild virus re-excretion in the latent carrier.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A slight transient rise in temperature (1°C) can commonly occur up to 5 days post vaccination.
An increase of nasal discharge can be commonly observed after intranasal vaccination.
In very rare cases hypersensitivity reactions can occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) 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 leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

Reconstitute the lyophilisate with the solvent

Number of doses per vial	Volume (ml) of solvent needed
5	10
10	20
25	50
50	100
100	200

Dosage: a single dose of 2 ml reconstituted vaccine per animal.

Method of administration:
- from the age of 3 months onward: intranasal use or intramuscular use.
- at an age between 2 weeks and 3 months: intranasal use.

Primary vaccination:
- Basic vaccination:
Vaccinate each animal from 3 months of age onwards with one single dose.
- Early protection schedule:
When the first vaccination is given between the age of 2 weeks and 3 months, a second vaccination should be given at an age of 3-4 months.

First revaccination:
The first revaccination should be given 6 months after primary vaccination. Bovilis IBR marker inac can alternatively be used for this revaccination.

Subsequent revaccinations:
All following revaccinations should be given at an interval no greater than 12 months. Bovilis IBR marker inac can alternatively be used for these revaccinations.

The product literature of Bovilis IBR marker inac should be consulted before using it for revaccination.

For revaccination, the lyophilisate may be reconstituted shortly before use with Bovilis BVD for use in cattle from 15 months of age (i.e. those that have previously been vaccinated separately with Bovilis IBR marker live and Bovilis BVD).The following instructions should be used:

Bovilis IBR marker live		Bovilis BVD
5 doses	+	10 ml
10 doses	+	20 ml
25 doses	+	50 ml
50 doses	+	100 ml

A single dose (2 ml) of Bovilis IBR marker live mixed with Bovilis BVD is given intramuscularly.
The product literature of Bovilis BVD should be consulted before administration of the mixed products.

Shelf life after mixing with Bovilis BVD: 3 hours.

9. ADVICE ON CORRECT ADMINISTRATION

For intranasal use (1 ml in each nostril), the use of a nozzle is recommended.
Use sterile vaccination equipment free from disinfectants. To prevent the spread of any infective agents the intranasal equipment should be changed at each animal.

Visual appearance after reconstitution
- In solvent: colourless to slightly opaque solution.
- In Bovilis BVD: as specified in the product information for Bovilis BVD alone.
-

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Lyophilisate:
Store in a refrigerator (2 °C - 8 °C).
Do not freeze.
Protect from light.

Solvent:
Store below 25 °C if stored independently from the vaccine.
Do not freeze.

Shelf life after reconstitution according to directions: 3 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The presence of maternal antibodies can influence the efficacy of the vaccination. Therefore it is recommended to ascertain the immune status of calves before vaccination is started.

Special precautions for use in animals:
Vaccinate only healthy animals.
After intranasal use, the vaccine virus may spread to in-contact cattle. Cattle which need to remain totally free from BHV-1 antibodies should be separated from intranasally vaccinated 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 the label to the physician.

Pregnancy, lactation and fertility:
Can be used during pregnancy and lactation.
No information is available on the use of this vaccine in breeding bulls.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data - in cattle from 3 weeks of age onwards - are available which demonstrate that this vaccine can be administered on the same day but not mixed with Bovipast RSP.

Safety and efficacy data are available which demonstrate that for the intramuscular re-vaccination - in cattle from 15 months of age onwards (i.e. those that have previously been vaccinated separately with Bovilis IBR marker live and Bovilis BVD) - this vaccine can be mixed and administered with Bovilis BVD. The product literature of Bovilis BVD should be consulted before administration of the mixed products. The adverse effects observed after administration of one dose or an overdose of the mixed vaccines are not different from those described for the vaccines administered separately.
When mixed with Bovilis BVD at re-vaccination, the demonstrated efficacy claims for Bovilis IBR marker live are as follows:

- Active immunisation of cattle to reduce the fever induced by an infection with BHV-1 and to reduce nasal excretion of field virus.
- Duration of immunity : 12 months demonstrated by serological data.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.
Do not use together with immunosuppressive agents.

Overdose (symptoms, emergency procedures, antidotes):
At 10-fold overdose, no other effects than described under section 6 have been observed.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except the diluent supplied for use with the veterinary medicinal product or with Bovilis BVD (for revaccination only).

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

The vaccine stimulates active immunity 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 this product and cattle infected with BHV-1 field virus or vaccinated with conventional non-marker BHV-1 vaccines.

Pack sizes:
Cardboard box with 1 glass vial of lyophilisate (5 doses) and 1 glass vial of solvent (10 ml).
Cardboard box with 1 glass vial of lyophilisate (10 doses) and 1 glass vial of solvent (20 ml).
Cardboard box with 1 glass vial of lyophilisate (25 doses) and 1 glass vial of solvent (50 ml).
Cardboard box with 1 glass vial of lyophilisate (50 doses) and 1 glass vial of solvent (100 ml).
Cardboard box with 1 glass vial of lyophilisate (50 doses) and 1 PET vial of solvent (100 ml).
Cardboard box with 1 glass vial of lyophilisate (100 doses) and 1 glass vial of solvent (200 ml).
Cardboard box with 10 glass vials of lyophilisate (5 doses) and a cardboard box with 10 glass vials of solvent (10 ml).
Cardboard box with 10 glass vials of lyophilisate (10 doses) and a cardboard box with 10 glass vials of solvent (10 ml).
Cardboard box with 10 glass vials of lyophilisate (25 doses) and a cardboard box with 10 glass vials of solvent (50 ml).
Cardboard box with 10 glass vials of lyophilisate (50 doses) and a cardboard box with 10 glass vials of solvent (100 ml).
Cardboard box with 10 glass vials of lyophilisate (50 doses) and a cardboard box with 10 PET vials of solvent (100 ml).
Cardboard box with 10 glass vials of lyophilisate (100 doses) and a cardboard box with 10 glass vials of solvent (200 ml).

Not all pack sizes may be marketed.

Veterinary medicinal product subject to prescription.

Approved 17 July 2020