SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR Marker Inac suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE 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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Formaldehyde	0.6 – 1.0 mg
Trometamol	
Sodium chloride	
Veggie medium	
Water for injections	

Pink turbid suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Efficacy has not been demonstrated in the face of maternally derived antibodies.

3.5 Special precautions for use

Special precautions for safe use in the target species:
None.

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.

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):	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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.
{< > to be adjusted nationally}

3.7 Use during pregnancy, lactation or lay

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

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.

3.9 Administration routes and dosage

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

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.

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

At a two-fold overdose, no effects other than those described in section 3.6 have been observed.

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

<Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.>

Official control authority batch release may be required for this product according to national requirements.
{< > to be adjusted nationally}

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AA03

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.

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

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

Vials of glass (hydrolytic type I) or plastic (polyethylene-terephthalate) closed with a rubber stopper and an aluminium cap.

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.

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>.
{< > to be adjusted nationally}

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}
{to be completed nationally}

7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}
{to be completed nationally}

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

{MM/YYYY}
{to be completed nationally}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

[BE, CZ, DE, EE, ES, FR, HU, IT, LT, LU, LV, NL, PL, SK, UK(NI)]: Veterinary medicinal product subject to prescription.
[IE]: 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).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS 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

{Name or company name or logo name of the marketing authorisation holder}
{to be completed nationally}

14. MARKETING AUTHORISATION NUMBERS

{national number}
{to be completed nationally}

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

{Name or company name or logo name of the marketing authorisation holder}
{to be completed nationally}

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.

B. 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:
<Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.>
{< > to be adjusted nationally}

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: {< > to be adjusted nationally}

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 or <household waste>.
{< > to be adjusted nationally}

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.>
{< > to be adjusted nationally}

13. Classification of veterinary medicinal products

[BE, CZ, DE, EE, ES, FR, HU, IT, LT, LU, LV, NL, PL, SK, UK(NI)]: Veterinary medicinal product subject to prescription.

[IE]: Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

{to be completed nationally}

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. Date on which the package leaflet was last revised

{MM/YYYY} {to be completed nationally}

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

16. Contact details

Marketing authorisation holder <,> <and> < manufacturer responsible for batch release> <and contact details to report suspected adverse events>:
{< > to be adjusted nationally}

<Manufacturer responsible for batch release:> {< > to be adjusted nationally if included in the above}
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

<Local representative< and contact details to report suspected adverse events>:>
{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

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.

{to be completed nationally}