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.

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

Not applicable.

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 product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBERS

Vm 06376/5008
Vm 06376/3008

8. DATE OF FIRST AUTHORISATION

19 July 2006

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

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 05 November 2025