1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR marker inac suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substance:
Inactivated bovine herpesvirus type 1 (BHV-1) strain GK/D (gE^-)[*]: 60 ELISA units[**].

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

Adjuvant:

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

Excipient:

Formaldehyde	0.6 - 1.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Pink turbid suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the 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
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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

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 the case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy and lactation

Can be used during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

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

Intramuscular injection, 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Administration of a double dose does not cause other effects than after a single dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: inactivated viral vaccine, vaccine against bovine rhinotracheitis virus (IBR).
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium phosphate
Aluminium hydroxide
Formaldehyde
Trometamol
Sodium chloride
Veggie medium
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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.

6.4. Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

6.5 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.

6.6 Special precautions for the disposal of unused medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
as represented by the national companies in the concerned Member States.

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}
Date of last renewal: {DD/MM/YYYY}

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Bovilis IBR marker inac is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use Bovilis IBR marker inac must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.