1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR marker live, lyophilisate and solvent for suspension for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml reconstituted vaccine contains:

Active substance(s)
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%

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension.
Lyophilisate: off-white to light pink-coloured pellet.
Solvent: colourless solution

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

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.

Specific information:
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.

4.3 Contraindications

None.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy animals.
After intranasal administration, 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.

4.6 Adverse reactions (frequency and seriousness)

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 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, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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 onwards: intranasal use or intramuscular use.
- at an age between 2 weeks and 3 months: intranasal use.
For intranasal use (1 ml in each nostril), the use of a nozzle is recommended.

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.

Shelf life after mixing with Bovilis BVD: 3 hours

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.

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

At 10-fold overdose, no other effects than described under section 4.6 have been observed.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live herpes virus vaccine
ATC-vet code: QI02AD01. To stimulate active immunity against 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Veggie medium
Sorbitol
Monosodium glutamate
Glycine
Amine#1
Disodium phosphate dihydrate
Water for injections

Solvent:
Sucrose
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Sodium chloride
Water for injections

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
Lyophilisate: 36 months
Solvent: in glass vials: 60 months; in PET vials: 18 month

Shelf life after reconstitution according to directions: 3 hours.

6.4 Special precautions for storage

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 lyophilisate.
Do not freeze.

6.5 Nature and composition of immediate packaging

Lyophilisate:
Vials of glass (hydrolytic type I) closed with a rubber stopper and metal cap.

Solvent:
Vials of glass (hydrolytic type II) or plastic (polyethylene terephthalate) closed with a rubber stopper and metal cap. Solvent may be packed together with the lyophilisate or separately.

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.

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

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 Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/172/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th October 2002
Date of last renewal: 22nd March 2011

10 DATE OF REVISION OF THE TEXT

June 2017