

## **PACKAGE LEAFLET**

### **Bovilis IBR marker inac suspension for injection for cattle**

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

Marketing authorization holder:

Intervet International BV  
Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands

As represented by the national companies  
in the Concerned Member States

Manufacturer responsible for batch release:

Intervet International BV  
Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands

#### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Bovilis IBR marker inac suspension for injection for cattle

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

Each dose of 2 ml contains:

Inactivated bovine herpesvirus type 1 (BHV-1) strain GK/D (gE<sup>-</sup>): 60 ELISA units\*\*

Aluminium-phosphate and -hydroxide (Al<sup>3+</sup>): 6.0 - 8.8 mg

Formaldehyde: 0.6 - 1.0 mg

\* gE<sup>-</sup>: glycoprotein E negative

\*\* inducing 6.1 - 11.1 log<sub>2</sub> virus neutralising units in the mouse potency test.

Pink turbid suspension.

#### **4. INDICATION(S)**

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.

#### **5. CONTRAINDICATIONS**

None.

## **6. ADVERSE REACTIONS**

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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Cattle.

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

2 ml per animal, intramuscular injection.

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 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 PERIOD**

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.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

## **12. SPECIAL WARNING(S)**

Special warnings for each target species:

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

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 case of accidental self injection, seek medical advice immediately and show the package leaflet or 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 (symptoms, emergency procedures, antidotes):

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

Incompatibilities:

Do not mix with any other veterinary medicinal product.

## **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**

{ date }

## **15. OTHER INFORMATION**

Bovilis IBR marker inac 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.

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.

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.