

## **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 of 2 ml contains:

**Active substance:**

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

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

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

**Adjuvant:**

Aluminium-phosphate and -hydroxide (Al<sup>3+</sup>)      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**

MSD Animal Health UK Limited  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

**8. MARKETING AUTHORISATION NUMBER**

Vm 01708/3039

**9. DATE OF FIRST AUTHORISATION**

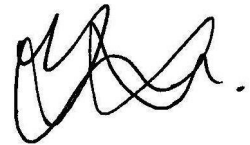
19 July 2006

**10. DATE OF REVISION OF THE TEXT**

October 2023

**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.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 10 October 2023