



# AFTOMUNE<sup>®</sup>

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Product information

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## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AFTOMUNE – Bivalent vaccine against foot-and-mouth disease

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Suspension of O1 Campos and A24 Cruzeiro foot-and-mouth disease virus antigens, replicated in BHK21Cl13 cells, inactivated with 2-bromoethylimine – BEI (first order inactivator), purified, concentrated and, later, emulsified in an oil adjuvant.

## 3. PHARMACEUTICAL FORM

Water-in-oil injectable emulsion, packaged in 30 mL or 100 mL vials (15 doses or 50 doses, respectively) closed with rubber stoppers, with a inviolable aluminium seal.

The labels are printed using the *silk screen* method, with the batch number, manufacturing date and expiry/due date indelibly printed.

## 4. CLINICAL PARTICULARS

### 4.1 | Target species

Cattle and buffaloes

### 4.2 | Indications for use, specifying the target species

Immunization of cattle and buffaloes against foot-and-mouth disease.

Agitate the vial before use.

Administer a dose of 2 mL in cattle and buffaloes via the intramuscular or subcutaneous route in the region of the neck plate (middle third).

### 4.3 | Contraindications

None.

### 4.4 | Special warnings for each target species

The animals are vaccinated according to the rules that regulate the official campaigns of the local health authority.

### 4.5 | Special precautions for use

- Read the insert carefully before using the product and respect the indications and dosage.
- Store the product in its original vial.

- Do not store near food, beverages, other drugs, personal care or household products.
- Do not smoke or eat while handling the product.
- Pay attention to the expiration date and the storage conditions as mentioned in the insert.
- Do not use the product after the expiration date.
- Do not reuse empty packaging.
- The disposal of products or their empty packaging must be done in accordance with the current environmental legislation.
- As it is an emulsion, it must be agitate before use.
- As it is a parenteral application, strict asepsis measures must be taken.
- Use sterile syringes and needles and do not apply other products in the same syringe.
- Keep under constant refrigeration between 2°C and 8°C until application. Transport in thermal insulation boxes with ice and shelter from the sun.
- Use disposable gloves to apply the product to the animal.
- Always wash your hands after handling any veterinary drug.
- Avoid contact with skin and eyes. In case of accidental contact with the skin, wash thoroughly with water and soap. In case of accidental contact with the eyes, rinse with plenty with water.
- In case of accidental ingestion or injection, seek medical attention immediately, taking the product packaging with you.

#### **4.6 | Adverse reactions (frequency and seriousness)**

The inoculation of oily vaccines can determine, in some hyper-reactive animals, postvaccination reactions of the hypersensitizing type. In these sensitive animals, the formation of a nodule at the application site may occur, sometimes accompanied by pain, which will disappear in a few days.

In case of any adverse event, the veterinarian must be communicated.

#### **4.7 | Use during pregnancy, lactation or lay**

The animals are vaccinated according to the rules that regulate the official campaigns of the local health authority.

#### **4.8 | Interaction with other medicinal products and other forms of interaction**

AFTOMUNE® vaccine can be administered in parallel with the administration of antiparasitics, vitamins and minerals, as long as the inoculation sites are different.

## **4.9 | Amounts to be administered and administration route**

**Doses:** 2 mL per animal.

The animals are vaccinated according to the rules that regulate the official campaigns of the local health authority.

## **4.10 | Overdose (symptoms, emergency procedures, antidotes), if necessary**

No overdose data were provided.

## **4.11 | Withdrawal period(s)**

Not applicable.

# **5. IMMUNOLOGICAL PROPERTIES**

Not applicable.

# **6. PHARMACEUTICAL PARTICULARS**

## **6.1 | Shelf life**

18 months of shelf life.

## **6.2 | Special precautions for storage**

Store between 2°C and 8°C. Do not freeze.

Protect from direct sunlight and in original packaging.

## **6.3 | Nature and composition of immediate packaging**

Glass vials containing 100 mL (50 doses) and 30 mL (15 doses) of product.

## **6.4 | Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Any unused veterinary drug or waste materials derived from such veterinary drug should be disposed in accordance with the local requirements.