FOR VETERINARY USE ONLY

MASTIDOLL-3

EMULSION FOR INJECTION

Dollvet

INACTIVATED VACCINE FOR PROTECTION AGAINST SUBCLINICAL AND CLINICAL MASTITIS INFECTIONS

COMPOSITION:

Each vaccine dose (2 ml) consists of:

Inactive *Escherichia coli D5* antigen	≥ 1/40 ELISA seropositive*
Inactive *Staphylococcus aureus* antigen	≥ 1/40 ELISA seropositive*
Inactive *Mycoplasma bovis* antigen	≥ 1/40 ELISA seropositive*
Oil adjuvant	50% (w/w)
Formaldehyde	< 0.4% (v/v)
Physiological saline	Up to 1 ml

*ELISA seropositive minimum serum dilution rate in vaccinated rabbit serum

INDICATIONS:

MASTIDOLL-3 is a bacterial, oil-adjuvanted and inactive combination vaccine used for protection of cows and heifers against subclinical and clinical mastitis infections caused by *Escherichia coli*, *Staphylococcus aureus* and *Mycoplasma bovis*.

ADMINISTRATION METHOD AND DOSAGE:

For cows and heifers: 2 ml intramuscular injection into neck muscles. Animals that have not previously been vaccinated should be given 2 injections at an interval of 21 days. Then they should be vaccinated every 6 months. Heifers can be vaccinated 2 months prior to first calving, and cows can be vaccinated any time.

SPECIFIC CLINICAL INFORMATION AND WARNINGS FOR TARGET SPECIES:

No adverse reactions were observed during tests where the vaccine was administered in line with the target animal species and as specified in the leaflet.

ADVERSE REACTIONS:

In rare cases of anaphylactic reactions, symptomatic treatment should be applied. No side effects were observed in harmlessness and toxicity studies in experimental and target animals. In some vaccinated animals, temporary hazelnut-sized swellings may be seen at the injection site, and a temporary increase in body temperature may occur.

INTERACTION WITH OTHER MEDICINAL PRODUCTS:

No information is available on the safety and efficacy of this vaccine for use with other biological products.

OVERDOSE SYMPTOMS, EMERGENCY PROCEDURES AND ANTIDOTES:

The vaccine is an inactivated one. Safety studies in booster applications have shown that it is safe.

WITHDRAWAL PERIODS:

0 days.

CONTRAINDICATIONS:

It is not recommended to vaccinate infected animals.

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GENERAL WARNINGS:

"Keep out of reach of children"

"Consult a veterinarian upon an unexpected effect"

PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VACCINE AND RECOMMENDATIONS FOR VETERINARIANS:

- Vaccines should be stored at +2/+8°C and shaken well before use. Remaining vaccines should not be used.
- Necessary precautions should be taken to ensure the vaccines do not overheat.
- In case of an accidental injury of the person administering the vaccine, the wound should be disinfected locally, and medical attention should be sought.
- The vaccine should only be administered by a veterinarian or a veterinary technican under the supervision of a veterinarian.

STORAGE CONDITIONS AND SHELF LIFE:

Stored at + 2/8ºC, and in the dark. Shelf life is 24 months. Opened vials should be used within 6-8 hours.

DISPOSAL OF WASTE/UNUSED PRODUCTS AND RECOMMENDATIONS FOR NON-TARGET SPECIES:

Unused or opened but not completely used vaccines are disposed of as medical waste, according to the provisions of the applicable waste regulations.

PRESENTATION:

The vaccine is packed as 2 ml (1 dose) and 4 ml (2 doses) in 6R Type I amber colored glass vials, as 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) and 100 ml (50 doses) in Type II amber-colored glass, or as 20 ml (10 doses), 50 ml (25 doses) and 100 ml (50 doses) in white plastic vials. Glass and plastic bottles are labeled as closed with the same butyl stoppers and aluminum caps. Vaccine vials are available on the market as 2 ml (1 dose) and 4 ml (2 doses) vials in cardboard boxes of 5 and 10, and glass and plastic vials of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) and 100 ml (50 doses) in single-unit cardboard boxes. Not all forms of packaging may be placed on the market.

LEAFLET APPROVAL DATE: 20.02.2020

DATE OF MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY: 20.02.2020

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

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