



ONLY USED FOR ANIMAL HEALTH

**LAXYDOLL-oil**

INJECTABLE EMULSION

**INACTIVE AGALACTIAE VACCINE****COMPOSITION:**

**Name and brief description of the veterinary biological product:** LAXYDOLL-oil is an inactive vaccine with oil adjuvant prepared by from Mycoplasma agalactiae vaccine strain (99M-AIK ).

**Name and power of active substances, and auxiliary substances, if it exist:**

The dose content (1 ml) of the vaccine is at least as follows.

Components	Quantity (1 ml)
Inactive 99M-AIK <sub>2</sub> Mycoplasma agalactiae	1x10 <sup>9</sup> CFU/dose*
Oil adjuvant	0,5 ml/dose
Phenol	3 µl/dose
Physiological Saline Water (FTS)	Up to 0,5 ml

\* Colony count before inactivation

**INDICATIONS:**

It is used for the protection of sheep and goats against contagious agalactiae. Safe for vaccination of sheep and goats during pregnancy and lactation.

**CONTRAINDICATIONS:**

It should not be administered to infected animals or animals within the incubation period.

**ADVERSE EFFECTS:**

Nodules ranging from the size of nuts to the size of walnuts, which are seen at the vaccine administration area and subsequently disappear, are normal vaccine reactions.

Any injection of mycoplasmic antigens, even if they are inactive, is likely to cause hypersensitivity reactions. In these cases, symptomatic treatment should be applied.

**TARGET SPECIES:**

Sheep and goats

**METHOD OF ADMINISTRATION, AND DOSE, AND VACCINATION SCHEDULE:**

- The vaccine is administered to the hairless and immobile inactive armpit area behind the scapula via subcutaneous or intramuscularly.
- The administration dose is 1 ml

ANIMAL SPECIES	VACCINE ADMINISTRATION AREA	VACCINE DOSE AND VACCINATION PERIOD	
		1st VACCINATION	2nd VACCINATION (After a year)
SHEEP / GOAT	Hairless and immobile area in armpit subcutaneously or intramuscularly	1 ml /SC/IM	1 ml /SC/IM

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**INACTIVE AGALACTIAE VACCINE****WITHDRAWAL PERIOD FOR ANIMAL ORIGIN PRODUCTS:**

According to Article 10/2 of the European Union Directive 2001/82 / EC, unless otherwise stated the withdrawal period is minimum 7 days for milk and minimum 28 days for meat.

**PRESENTATION:**

The vaccine is packaged in amber colored type II glass vials in 10 ml (10 doses), 20 ml (20 doses), 50 ml (50 doses) and 100 ml (100 doses) each bottle is packaged in individual box.

**STORAGE CONDITIONS AND SHELF LIFE :**

It is stored in the dark at 2 / 8°C. Its shelf life is 2 years. Do not freeze.

**WARNINGS:**

In rare cases, adrenergic and antihistamine preparations should be administered against anaphylactic shocks that may occur shortly after vaccination in susceptible animals.

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

The vials of the vaccine should be shaken vigorously and this process should be continued at intervals during the administration period. Each opened vaccine vial should be used within the same day. Any remain or empty vaccine vials should be disposed of properly. Vaccines that have been exposed to high temperature and sunlight and those that are frozen or of which packaging integrity has been impaired should never be used. Animals to be vaccinated should be healthy. Asepsis and antisepsis should be taken into consideration in vaccine administrations. The vaccine should be applied only by a veterinarian or by a health technician under the veterinarian's supervision.

**DISPOSAL OF WASTE AND UNUSED PRODUCTS:**

Vaccines that are not used and left open for use are disposed of as medical waste according to the applicable waste regulations.

“Keep out of reach of children”

“In case of an unexpected effect, consult the veterinarian”



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**NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:**

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