

FOR VETERINARY USE ONLY

# LAXYDOLL -oil



INACTIVATED AGALACTIA VACCINE

## Dollvet

### EMULSION FOR INJECTION

LAXYDOLL-oil is an oil-adjuvanted inactivated vaccine prepared with *Mycoplasma agalactiae* vaccine strain (99M-AIK2).

#### COMPOSITION:

Each dose (1 ml) contains at least:

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

\* Colony count before inactivation

#### INDICATIONS:

It is administered for protection against contagious Agalactia of sheep and goats. It is safe to be administered to sheep and goats during pregnancy and lactation.

#### CONTRAINDICATIONS:

It should not be administered to infected animals or those in incubation period.

#### SIDE EFFECTS:

Nodules, varying in size from nuts to walnuts, that are seen at the vaccine administration site, then disappear, are normal vaccine reactions.

Injection of mycoplasmic antigens, even if they are inactive, is likely to cause hypersensitivity reactions. In such a case, symptomatic treatment should be applied.

#### TARGET SPECIES:

Sheep and goats.

#### DOSAGE, METHOD AND ROUTE OF ADMINISTRATION AND VACCINATION SCHEDULE FOR EACH SPECIES:

- The vaccine is administered by subcutaneous or intramuscular injection into the axillary hairless and immobile area behind the scapula.
- Each vaccine dose is 1 ml.

ANIMAL SPECIES	ADMINISTRATION SITE	DOSAGE and VACCINATION SCHEDULE	
		1st ADMINISTRATION	2nd ADMINISTRATION (1 year later)
SHEEP/GOATS	Hairless and immobile axillary area or intramuscular	1ml/SC/IM	1ml/SC/IM

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#### WITHDRAWAL PERIODS:

The withdrawal period after vaccination is minimum 7 days for milk and minimum 28 days for meat.

#### PRESENTATION:

The vaccine is packed in amber colored 10 ml (10 doses), 20 ml (20 doses), 50 ml (50 doses) and 100 ml (100 doses) Type II glass vials, placed in 1-unit cardboard boxes.

#### STORAGE CONDITIONS AND SHELF LIFE:

Stored at +2/8°C, and in the dark. Shelf life is 2 years. Do not freeze.

#### WARNINGS:

In rare cases of anaphylactic shock developing shortly after vaccination in susceptible animals, adrenergic and antihistaminic preparations should be administered.

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

- Before starting vaccination, the vial should be shaken well, and at intervals throughout the vaccination process.
- Once opened, the vial should be used within the same day. Partly used or empty vials should be disposed of as per regulated.
- Vaccines exposed to high heat or sunlight, those frozen or packaging integrity broken should never be used.
- Animals to be vaccinated must be in good health.
- Asepsis and antiseptics principles should be followed during administration.
- The vaccine should only be administered by a veterinarian or a veterinary technician under the supervision of a veterinarian.

#### DISPOSAL OF WASTE/UNUSED PRODUCTS:

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

#### GENERAL WARNINGS:

Keep out of reach of children.

Consult a veterinarian upon an unexpected effect.

FINAL LEAFLET APPROVAL DATE: 23.12.2010

DATE OF MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY: 23.12.2010

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

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