FOR VETERINARY USE ONLY

ORFDOLL

LIVE ECTHYMA VACCINE

Dollvet

LYOPHILISATE FOR SUSPENSION FOR INJECTION AND SOLVENT

COMPOSITION:

Each dose of vaccine and solvent content is as follows:

LYOPHILISATE FOR SUSPENSION FOR INJECTION

Ingredients	Quantity	Function
Attenuated E(P)CK$_{22}$ strain	$10^{3.5}$ TCID$_{50}$/dose	Immunizing antigen
Lactalbumin hydrolysate	0,25 mg/dose	Preservative
Sucrose	0,50 mg/dose	

SOLVENT FOR PARENTERAL USE

Ingredients	Quantity	Function
Glycerol	0,05 ml/dose	Reconstitution solvent
Water for injection	0,05 ml/dose	
Patent Blue V	0,01 mg/dose	

INDICATIONS:

ORFDOLL is used against ecthyma disease, which causes infection of the mouth, lips, eyes and skin in sheep, goats, lambs and kids.

ADMINISTRATION METHOD AND DOSAGE:

The vaccine is administered to sheep, goats, lambs and kids of all ages as of the first week, by crossing the bare skin in the Regio inguinal (the inner part of the back leg) 0.5-1 cm long and in 3-4 lines and in a way that is deep enough to cross the first layer of the skin but does not cause bleeding, and by dripping 2 drops (0,1 ml) into the scarred skin and waiting for a few seconds. For the preparation of the vaccine, 2 ml solvent is taken with a sterile syringe, transferred into the dry vaccine bottle, shaken without foaming and added to the reconstitution solvent again by drawing 2-3 times with the syringe. Then the dropper, packed separately, is inserted into the bottle containing the dissolved vaccine. Scarring the administration site is done with the metal scarring apparatus in the package.As the vaccine provides an immunity of maximum 12 months, it is recommended to repeat the administration every year with the same dosage. The reconstituted vaccine should be used on the same day (within six hours).

WARNINGS FOR TARGET SPECIES:

The vaccine should be administered collectively to lambs and kids of all ages, immediately after birth in places where the disease occurs, and for protective purposes after the completion of all births in other places. Preventive vaccination is recommended in areas of disease outbreak. Infected animals should be separated from the herd, and the remaining ones should be vaccinated.

ADVERSE REACTIONS:

3-4 days after vaccination, small orf-like lesions (vesicles, pustules, then crusting) on the scarification site and a temporary rise in body temperature may be observed.

INTERACTION WITH OTHER MEDICINAL PRODUCTS:

The safety and efficacy of this vaccine when used with other vaccines (on the same day or at different times) is unknown. In addition, corticosteroids or other immunosuppressive drugs should not be used before or within 28 days after vaccination.

OVERDOSE SYMPTOMS, EMERGENCY PROCEDURES AND ANTIDOTES:

Safety studies have shown that the vaccine is safe in overdose administration (10 doses).

WITHDRAWAL PERIODS:

The withdrawal period for food-producing animals is 14 days.

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CONTRAINDICATIONS:
The vaccine has no contraindications.

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:
- The vaccine can cause skin infection in humans, therefore rubber gloves should be worn during vaccination and hands and arms should be washed thoroughly afterwards.
- In case of an accidental self-administration (injection or scarring) or contamination of the skin or inside eyes, medical care should be sought immediately.
- The vaccine should only be administered by a veterinarian or a veterinary technician under the supervision of a veterinarian.

STORAGE CONDITIONS AND SHELF LIFE:
The vaccine should be stored at + 2/8ºC, and in the dark. Do not freeze. The solvent should be stored at temperatures below 25°C.
Shelf life is 2 years.

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.

PRESENTATION:
The vaccine is available in Type I glass vials containing 50, 100 and 200 doses of lyophilisate and Type II glass vials containing 5, 10 and 20 ml reconstitution solvent. The vials are packed with butyl stoppers and aluminum caps, and thus labeled.
The vials containing lyophilized vaccine and reconstitution solvent are packaged in individual cardboard boxes with leaflet, dropper and apparatus for scarification. Not all forms of packaging may be placed on the market.

LEAFLET APPROVAL DATE: 04.11.2019

DATE OF MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY: 04.11.2019

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