ONLY USED FOR ANIMAL HEALTH

ORFDOLL

INJECTABLE SUSPENSION LYOPHILIZATE AND DILUENT

LIVE ECTHYMA VACCINE

COMPOSITION:

Each dose of vaccine and diluent content is as follows:

Injectable Suspension lyophilizate

Components	Amount	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	Preservative

Diluent for parenteral administration

Components	Amount	Function
Glycerol	0,05 ml/dose	Diluent
Water for injection	0,05 ml/dose	Diluent
Patent Blue V	0,01 mg/dose	Diluent

INDICATIONS:

ORFDOLL vaccine is used for the protection against contagious ecthyma , which infects mouth, lips, eyes and skin in sheep, goats, lambs and kids.

METHOD OF ADMINISTRATION AND DOSE:

The vaccine is administered to lambs, kids, sheep and goats of all ages from 1 week old. The vaccine is administered to the bare skin as 0.5-1 cm long and 3-4 lines in regio inguinal (inner part of the back leg) by scratching it deep enough to pass the first layer of the skin, but without bleeding, and by applying 2 drops (0.1 ml) of the scratched skin and waiting for a few seconds. For this purpose, when using the vaccine, take 2 ml of the diluent with a sterile syringe and transfer it to the dry vaccine vial, shake it without foaming, and add it to the diluent by pulling it 2-3 times with the syringe. Then the individually packed dropper is passed into the dissolved vaccinated flask. The scratching process is done with the metal scratching apparatus inside the package.Since the immunization period of the vaccine is maximum 12 months, vaccination is recommended to be repeated at the same dose every year.
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 after the completion of births for protective purposes. It is recommended to administer protective vaccination at disease sites. Infected animals should be separated from the herd and the remaining animals should be vaccinated.

UNDESIRABLE EFFECTS:

On the 3 and 4 days after vaccination, mild Orf-like lesions (vesicle, pustule, and later cicatrize) and a temporary increase in body temperature occur at the scarification site where the vaccine is applied.

DRUG INTERACTIONS:

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

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OVERDOSE, SYMPTOMS, IF OCCURRED, PRECAUTIONS AND ANTIDOTES:

In safety studies, the vaccine has been shown to be safe in administering an overdose (10 doses).

WITHDRAWAL PERIOD FOR ANIMAL ORIGIN PRODUCTS:

Withdrawal period for animal origin products is 14 days.

CONTRAINDICATIONS:

The vaccine has no contraindications.

SPECIAL 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 after vaccination. In case of accidental self-application (injection or scratch), skin or eye contact, medical attention should be sought immediately. The vaccine should be applied only by a veterinarian or by a health technician under the veterinarian's supervision.

STORAGE CONDITIONS AND SHELF LIFE :

The vaccine is stored at 2 / 8ºC and in the dark. Do not freeze. The diluent is stored at a temperature below 25 ° C. Its shelf life is 2 years.

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.

PRESENTATION:

The lyophilized vaccine is available in packages containing 50 doses, 100 doses and 200 doses in Type I glass vials and 5 ml, 10 ml and 20 ml diluent in Type II glass vials. The vials are packaged and sealed with a butyl stopper and an aluminum cap.
Vials containing lyophilized vaccine and diluent are presented to the market in individual cardboard boxes, packaged together with the prospectus, dropper and apparatus for scarification. Not all forms of packaging may be placed on the market.

"Keep out of reach of children"

"In case of an unexpected effect, consult the veterinarian"

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

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
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