FOR VETERINARY USE ONLY

POXDOLL

LYOPHILIZED SHEEP-GOAT POX AND CATTLE LSD VACCINE

Dollvet

LYOPHILISATE FOR SUSPENSION FOR INJECTION AND RECONSTITUTION SOLVENT FOR PARENTERAL ADMINISTRATION

COMPOSITION:

For each dose (0.5 ml) it is as follows.

Lyophilisate for suspension for injection

Active Ingredients	Quantity	Function
Attenuated SPV(Bk) LK63 strain	≥$10^{2.5}$ $TCID_{50}$/dose	Immunizing antigen
Excipients		
Lactalbumin hydrolysate	0.25 mg/dose	Preservative
Sucrose	0.50 mg/dose	

Reconstitution solvent for parenteral administration

Ingredients	Quantity	Function
Sodium chloride	8.5 mg/ml	Reconstitution solvent
Disodium hydrogen phosphate heptahydrate	0.18 mg/ml	
Sodium dihydrogen phosphate dihydrate	0.06 mg/ml	
Water for injection	1 ml q.s.	

IMMUNOLOGICAL PROPERTIES:

Pharmacotherapeutic Group: Attenuated, lyophilized Sheep-Goat Pox, Bovine LSD vaccine

ATC Vet Code: QI02AD, QI03AD, QI04AD

POXDOLL vaccine is an attenuated, lyophilized vaccine used for preventive purposes against sheep and goat smallpox in sheep and goats and nodular exanthema of cattle (Lumpy Skin Disease) in cattle.

INDICATIONS:

POXDOLL vaccine is used for preventive purposes against sheep and goat smallpox in sheep and goats and nodular exanthema of cattle (Lumpy Skin Disease) in cattle. Immunity occurs 21 days after vaccination by forming a cellular and humoral immune response. The duration of immunity is 3 years following vaccination.

ADMINISTRATION ROUTE AND DOSAGE:

Add solvent to the lyophilized pellet. Shake without foaming. Add back to the solvent by drawing into the injector. The vaccine is administered by subcutaneous injection of 0.2 ml to 6-12 week old lambs and kids, 0.5 ml to animals older than 12 weeks and 3 ml to cattle older than 6 months. Subcutaneous vaccination made in cattle on the middle part of the side of the neck or the immobile area behind the shoulder, on the inside of the hind leg in sheep, and under the tail in goats.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES:

In sheep and goats, young animals under 6 weeks of age should not be vaccinated. In cattle, calves born to vaccinated animals should not be vaccinated before 6 months of age, while calves born to unvaccinated animals should be vaccinated before 6 months of age. The lyophilised vaccine must be used within 6 hours at the latest after reconstitution with reconstitution solvent. Infected animals, animals suspected of contamination during the incubation period and animals under stress should not be vaccinated. When the vaccine is to be used, the lyophilized pellet should be dissolved thoroughly with solvent using sterile syringes and the vaccine bottle should be shaken gently before each use. The vaccine should be brought to room temperature before administration. During vaccination, the vaccine bottle should be protected from the sun and kept on ice if possible. Aseptic needles and syringes must be used for each administration. The vaccine should only be administered by veterinarians or veterinary health technicians under the supervision of a veterinarian.

Use in pregnancy and lactation: It is suitable for use in pregnant animals.

UNDESIRABLE EFFECTS:

In some animals, hard or soft swellings with a diameter of 0.2-5 cm and a transient rise in body temperature may occur commonly (more than 1 in 100 animals but less than 10) at the site of vaccination.

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DRUG INTERACTIONS:

There is no information on the compatibility of this product when used with other vaccines. Therefore, the use of this product on the same day or at different times with other products has not been proven to be effective and safe.

SYMPTOMS, PRECAUTIONS AND ANTIDOTE IN CASE OF OVERDOSE:

Safety studies have shown that it is safe to administer a dose 10 times the normal administration dose.

WITHDRAWAL PERIODS:

0 day.

CONTRAINDICATIONS:

There are no contraindications.

GENERAL WARNINGS:

"Keep out of the reach of children."
"Consult a veterinarian in case of any unexpected effect."

PRECAUTIONS FOR THE PRACTITIONER AND RECOMMENDATIONS FOR VETERINARIANS:

There are no known adverse effects on human health, but the area should be cleaned and disinfected in case of injury during vaccine administration. If you accidentally inject yourself with the vaccine, seek medical advice immediately and show the instructions for use or the label of the product to your doctor.

STORAGE CONDITIONS AND SHELF LIFE:

Lyophilisate for injection: Store at + 2/8ºC and in the dark. Do not freeze. Shelf life is 36 months
Reconstitution solvent: Store in the dark and at temperatures lower than 25°C. Do not freeze. Shelf life is 36 months.
The reconstituted vaccine should be used within 6 hours.

DISPOSAL AND WARNINGS FOR NON-TARGET SPECIES:

Used or leftover product and waste materials resulting from the use of this product must be disposed of according to the relevant legislation. Any waste/excess material must not be mixed with domestic waste and waste water and must not be discharged into drainage systems and the environment.

PRESENTATION:

The vaccine is packaged in Type I colorless glass bottles containing 25, 50 and 100 doses of lyophilized pellets: 12.5 ml, 25 ml and 50 ml Type II amber glass bottles containing solvent for parenteral administration or white polypropylene plastic bottles. Glass and plastic bottles are labeled with a bromobutyl stopper and aluminum cap.
Lyophilized pellets are available in plastic vials of 20 pieces each or boxed/unboxed in styrofoam, solvent for parenteral administration is available individually boxed or unboxed in styrofoam.

APPROVAL DATE OF LEAFLET: 22.05.2025
DATE OF MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY: 25.06.2007

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

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200319/R.02