

FOR VETERINARY USE ONLY

# POXDOLL

LYOPHILIZED SHEEP AND GOAT POX VACCINE



## Dollvet

### LYOPHILISATE FOR SUSPENSION FOR INJECTION AND SOLVENT

POXDOLL is a lyophilized, live and attenuated vaccine used against pox disease in sheep and goats, and nodular exanthema (Lumpy Skin) disease in cattle.

#### PHARMACEUTICAL FORM:

Lyophilisate for suspension for injection

#### VACCINE COMPOSITION:

Following minimum quantities are used in each dose.

| Ingredients                | Quantity                            | Function           |
|----------------------------|-------------------------------------|--------------------|
| Attenuated SPV (Bk) strain | $10^{2.5}$ TCID <sub>50</sub> /dose | Immunizing antigen |
| Lactalbumin hydrolysate    | 0.25 mg / dose                      | Preservative       |
| Sucrose                    | 0.50 mg / dose                      |                    |

#### INDICATIONS:

POXDOLL is a vaccine used for protection against pox disease in sheep and goats, and nodular exanthema (Lumpy Skin) disease in cattle.

#### CONTRAINDICATIONS:

None.

#### ADVERSE REACTIONS:

In some animals, hard or soft swellings 0.2-5 cm in diameter at the injection site and a temporary rise in body temperature may be observed.

#### TARGET SPECIES:

Sheep, goats and cattle.

#### DOSAGE AND ADMINISTRATION METHOD AND ROUTE FOR EACH SPECIES:

The vaccine is administered by subcutaneous injection of 0.5 ml to 6-12-week old lambs and kids, 1 ml to animals older than 12 weeks and 6 ml to cattle older than 6 months.

#### WITHDRAWAL PERIODS:

None.

#### PRESENTATION :

Vaccine: Glass vials of 50 and 100 doses of lyophilized vaccine, packaged as 20 pieces in internal plastic or carton tray packaged in styrofoam box

Diluent: Amber glass or plastic bottles of 50 and 100 ml solvent packed in cardboard box.

#### STORAGE CONDITIONS AND SHELF LIFE:

Shelf life is 36 months at + 2/8°C and in the dark. The reconstituted vaccine should be used within two hours.

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#### WARNINGS:

Infected animals and animals suspected of being infected should not be vaccinated. The reconstituted vaccine should be used within two hours at the latest and shaken well before use. The vaccine is not administered to pregnant sheep and goats in the last 1/3 of pregnancy (in the last 6 weeks), in the first month following the birth, in places where the disease is not seen, and to kids and lambs under 6 weeks of age.

Calves born from vaccinated animals should not be vaccinated before 6 months of age. Calves born from unvaccinated animals should be vaccinated before they are 6 months of age. The safety of use in pregnant cattle has not been conclusively proven, therefore it is recommended not to be administered in the last 3 weeks of pregnancy.

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

Using sterile syringes, the lyophilized pellet should be homogenized, thoroughly dissolving it with the reconstitution solvent. During vaccination, special care should be taken not to contaminate the eyes or hands. In case of an accidental contact, the site should be cleaned with water and medical advice should be sought.

#### 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.

“Keep out of reach of children”

“Consult a veterinarian upon an unexpected effect”

LEAFLET APPROVAL DATE: 25.06.2007

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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