

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF PRODUCT**

Lumpyvax

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 1 ml dose of vaccine contains:

Freeze dried pellet:

Attenuated Lumpy skin disease virus (SIS Neethling-type), at least  $10^{4.0}$  TCID<sub>50</sub><sup>1</sup>

<sup>1</sup> TCID<sub>50</sub>: Tissue Culture Infectious Dose 50%

### **3. PHARMACEUTICAL FORM**

Lyophilisate and diluent for suspension.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target Species**

Healthy cattle should be vaccinated before the outbreak season.

Calves born from vaccinated cows should be vaccinated from 6 months of age.

Calves born from non-vaccinated cows may be vaccinated at any age.

#### **4.2 Indications for use**

For the prophylactic immunization of cattle against Lumpy skin disease.

Immunity starts to develop about 10 days after immunization and animal should be fully protected after 3 weeks (vaccine may not necessarily confer absolute immunity to all animals).

Annual revaccination.

#### **4.3 Contraindications**

Sick or cattle showing lesions should not be vaccinated.

#### **4.4 Special warning and precaution for use**

Vaccinated cows that develop an antibody response will confer maternal immunity to Lumpy skin disease by means of colostrum and this lasts for 4 to 6 months. Maternal antibodies in calves may have an influence on the vaccine efficacy.

Only healthy animals should be vaccinated

#### **4.5 Adverse reaction**

A temporary decrease in milk production may occur in very rare cases.

In regions in which Lumpy skin disease is not endemic, small lumps, sometimes accompanied by fever, may occur in very rare cases. These lumps usually resolve without treatment.

Injection site swelling may occur in very rare cases.

#### **4.6 Use during pregnancy and lactation**

Can be used during all stages of pregnancy.

#### **4.7 Interaction with other medicinal products and other forms of interaction**

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product.

#### **4.8 Amounts to be administered and administration route**

Reconstitute the lyophilisate with diluent provided for each pack size.  
Administer 1 ml of the vaccine per animal by subcutaneous injection.  
Use sterile injection equipment, free from traces of disinfectants.

#### **4.9 Overdose**

A slight transient rise in temperature may occur for 1-2 days.

#### **4.10 Withdrawal period**

**Meat:** Do not slaughter cattle for human consumption within 21 days of vaccination.\*

**Milk:** Zero days.

### **5. IMMUNOLOGICAL PROPERTIES**

To stimulate active immunity against Lumpy skin disease virus in cattle.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Lyophilisate:

Disodium phosphate dehydrate  
Potassium dihydrogen phosphate  
Peptone  
Lactose

Diluent:

Disodium phosphate dehydrate  
Potassium dihydrogen phosphate  
Sodium chloride  
Potassium chloride  
Purified water

#### **6.2. Incompatibilities**

Do not mix with any other veterinary medicinal product.

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\* 21 days is a standard withdrawal period set according to South African legislation for all vaccine products.  
If required by national legislation another withdrawal period may also be licensed e.g. 0 days

### **6.3. Shelf life**

Shelf life of the veterinary medicinal product as packed for sale:

Lyophilisate: 24 months.

The virus titre may drop over an extended storage period. Vaccine potency testing confirmed a minimum protective dose of  $\log_{10} 2.0$  TCID<sub>50</sub> (OIE, World Organisation for Animal Health).

Diluent: 2 years

Shelf life after reconstitution according to directions: use without delay.

### **6.4. Special precautions for storage**

Store in a refrigerator (2 °C - 8 °C).

Protect from light.

Do not freeze.

### **6.5. Nature and composition of immediate packaging**

Lyophilisate: glass type I closed with a butyl rubber stopper and sealed with an aluminium cap.

Diluent: High density polyethylene vial sealed with a combination cap (gold colour).

Pack sizes: Carton boxes with 20 or 100 doses of vaccine and diluent.

### **6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Dispose of waste material by boiling, incineration, or immersion in an appropriate disinfectant approved for use by the competent authorities.

## **7. MARKETING AUTHORISATION HOLDER**

Intervet South Africa (Pty) Ltd

Private Bag X2026

1600 Isando Gauteng

Republic of South Africa

## **8. MARKETING AUTHORISATION NUMBER(S)**

G3673 (Act 36/1947)

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

14/07/2009; renewal every three years.

## **10. DATE OF REVISION OF THE TEXT**

September 2017