

### 1. SUMMARY OF PRODUCT CHARACTERISTICS

#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovilis PPR

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

##### **Active substance(s):**

Freeze dried live attenuated PPR virus strain Sungri-96

#### 3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

#### 4. CLINICAL PARTICULARS

##### 4.1 Target species

Goat, sheep

##### 4.2 Indications for use

For active immunization of sheep and goats to prevent viremia, disease and mortality caused by Peste des Petits Ruminants virus. An onset of immunity at 2 weeks and duration of immunity of at least 6 years have been demonstrated.

##### 4.3 Contraindications

None.

##### 4.4 Special warnings

Only vaccinate healthy animals.

##### 4.5 Special precautions for use

###### **Special precautions for use in animals**

###### Preparation of vaccine

Allow the lyophilisate to dissolve completely before use (1dose/ml). Do not use chemical disinfectants.

###### **Special precautions to be taken by the person administering the veterinary medicinal product to animals**

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

##### 4.6 Adverse reactions (frequency and seriousness)

None known

##### 4.7 Use during pregnancy and lactation

Can be used during pregnancy.

**4.8 Interaction with other medicinal products and other forms of interaction**

None known

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other product. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product.

**4.9 Amounts to be administered and administration route**

Administer 1 dose (1ml) per animal of the re-suspended vaccine by subcutaneous injection. If animals are vaccinated below the age of 4 months in the face of maternal derived antibodies, it is advised to repeat the vaccination at a later age.

**4.10 Overdose (symptoms, emergency procedures, antidotes) (if necessary)**

None.

**4.11 Withdrawal period(s)**

Zero days for milk and meat.

**5. IMMUNOLOGICAL PROPERTIES**

Live attenuated vaccine virus for active immunisation of sheep and goats.

**6. PHARMACEUTICAL PARTICULARS****6.1 Incompatibilities**

None known

**6.2 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 15 months.

Shelf life after reconstitution: 3 hours.

The product remains stable when stored for 7 days at 30°C.

**6.3 Special precautions for storage**

Store at 2°C - 8°C

Protect from light

**6.4 Nature and composition of immediate packaging**

Glass vials closed with a rubber stopper containing 25, 50, 100 or 200 doses.

Glass or plastic vials closed with a rubber stopper containing 25, 50, 100 or 200 ml diluent

Not all pack sizes may be marketed.

**6.5 Special precautions for the disposal of unused 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**

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