SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

PESTE DES PETITS RUMINANTS VACCINE, LIVE
Strain: Nigerian 75/1 Strain
It is a live, Vero cell culture based viral vaccine, is recommended for vaccination against Peste
Des Petits Ruminants (PPR) disease. It has been lyophilized (freeze-dried) vials and sealed under vacuum to improve stability. It is available in different doses of 25, 50 and 100 doses.

It is supplied with diluents.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active Substance:
Peste Des Petits Ruminants Virus, Nigerian 75/1 strain……NLT $1x10^{2.5}$ $TCID_{50}$/ml

Adjuvant(s): N Z Amine ……..q.s
Lactose monohydrate…….q.s
Potassium Dihydrogen phosphate (KH_2PO_4)……..q.s
Di-potassium Hydrogen Phosphate (K_2HPO_4)……...q.s
Potassium hydroxide (KOH) …….q.s
L-Glutamic Acid……..q.s

3. PHARMACEUTICAL FORM

Lyophilized neat milky white cake, ready for reconstitution with the diluent.

Color after reconstitution; Milky white solution.

4. CLINICAL PARTICULARS

4.1 Target Species

Recommended for only sheep and goats aged above 4 months.

4.2 Method/ route of administration and direction of reconstitution

Vaccination should be done during the cooler part of the day. Store the diluent bottles in the refrigerator overnight, before use, to chill. Mixing is carried out by drawing small quantities of diluent from respective diluent bottles in the sterile syringe and then injecting this diluent in a freeze-dried vaccine vial. Shake the vial well and allow rehydrating the freeze-dried pellet and then drawing rehydrated vaccine and transferring it to the diluent bottle. Rinse the vaccine vial 2 times with the diluent in

similar manner as referred above. Draw the reconstituted vaccine with sterile syringe and needle. Reconstituted vaccine, during use should be stored in thermocol box with cool packs or ice and should be used immediately, Inject the 1 ml reconstituted vaccine per animal with SUBCUTANEOUS injection at mid neck region is advocated through an area of clean dry skin with all precautions taken.

4.3 Therapeutic Indications

The prophylactic action against Peste Des Petits Ruminants Virus.

4.4 Contraindications

No major contraindications reactions are noticed or found.

4.5 Special warnings for each target species

Not applicable.

4.6 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to birds

- Weak, debilitated and infested animals should not be vaccinated
- Deworming is recommended to sheep & goats to be vaccinated prior to vaccination.
- Vaccination should not be taken up in the areas of disease outbreak.
- Vaccine should be checked for cold chain before reconstitution & vaccination.
- Vaccination should be taken up only under the supervision of a registered veterinary practitioner.
- Part use of vial and storing for later use is not recommended.
- Recommended to use fresh sterile disposable needles are to be used for every sheep & goat.
- Vaccination of animals in advanced stage of pregnancy is not recommended.
- To maintain the quality of this product, it is essential that the directions and precautions for storage and use to be carefully followed.

7. Adverse reactions (frequency and seriousness)

- Generally, no adverse reactions are noticed.
- A few of vaccinated animals might show pyrexia and transient drop in milk yield.
- Vaccination could precipitate pre-incubating diseases in rare cases.

4.8 Use during pregnancy, lactation or lay

Avoid use in advanced pregnancy.

4.9 Interaction with other medicinal products and other forms of interaction

No other vaccine should be given simultaneously with the vaccine.

4.10 Overdose (symptoms, emergency procedures, antidotes)

Overdosing with vaccine is highly unlikely.

4.11 Withdrawal period

Zero days for milk, meat and offal.

5.1 IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live Viral Vaccine

ATC code: QI03AD01

5.2 PHARMACEUTICAL PROPERTIES

➢ **Clinical indication:**

To stimulate active immunity against Peste des petits ruminants (PPR) Virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Stabilizers:
  1) Potassium Hydroxide (KOH)
  2) Potassium Dihydrogen Phosphate (KH_2PO_4)
  3) Dipotassium Hydrogen Phosphate (K_2HPO_4)
- Preservatives:
  1) Lactose monohydrate
  2) N Z Amine
  3) L-Glutamic Acid

6.2 Incompatibilities

Do not mix with any other medicinal product (except diluent or other component recommended/supplied for use with the product

6.3 Shelf life

24 months from the date of manufacturing.

6.4 Special precautions for storage

Store between 2°C to 8 °C. Do not freeze. Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

- **Vials:** The final container is a TYPE I Neutral glass vials with aluminum flip off seal. Vial Capacity is 5 ml for 25, 50 and 100 doses. Vials are sterilized prior to use.

- **Stoppers:** Slotted Bromo butyl siliconised rubber stopper as per Q.C. Specifications. This is 13mm stopper for 5ml vial size. They are autoclaved prior to use.

- **Flip off Seals:** Aluminum water-colored Seals are clean with compressed air and then sterilized prior to use.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused product or waste materials should be disposed of in accordance to National requirements.

7. MARKETING AUTHORIZATION HOLDER

Hester Biosciences Africa Limited.
P.O Box 30216, TAMCO Industrial Area, Kibaha, Coast Region
Phone: +255 748 341 880
Email: hbal@hester.in
Website: www.hester.in

8. MARKETING AUTHORIZATION NUMBER

TAN 22 V 0205

9. DATE OF FIRST AUTHORIATION/ RENEWAL OF THE AUTHORIZATION

08th February, 2022

10. DATE OF REVISION OF THE TEXT