

Summary of Product Characteristics

Nisseiken PED Live Vaccine

1. Name of product

Nisseiken PED Live Vaccine

2. Pharmaceutical form

Lyophilized, live

3. Administration Route

Intramuscular injection

4. Main components

• Live attenuated porcine epidemic diarrhea virus P-5V strain cultured in Vero cell

5. Indication

Inhibition or reduction of porcine epidemic diarrhea in piglets through transfer of antibodies in milk from vaccinated sows.

6. Dosage, direction for use and route

Dissolve the lyophilized vaccine with the accompanying diluent. Intramuscularly inject two mL into pregnant sows twice with two to eight weeks interval.

The second injection should be given at about two weeks before farrowing.

7. Pharmaceutical particulars

a Shelf life;

See the package insert.

b Storage condition;

See the package insert.

c Nature and packing size of package

Lyophilized vaccine: 10 doses per one vial

Diluent: 20 mL (for 10 doses) per one vial

The lyophilized vaccine is yellowish to light pinkish white dried substance. When it is reconstituted with the accompanying diluent and shaken, it turns into an orangehued pale pink transparent homogeneous solution.

The diluent is colorless and transparent and pH is 7.0 to 7.4.

8. Name and address of manufacturer

Nisseiken Co., Ltd.

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All information are as of February, 2023