

Summary of Product Characteristics

Nisseiken Japanese Encephalitis Live Vaccine

1. Name of product

Nisseiken Japanese Encephalitis Live Vaccine

2. Pharmaceutical form

Lyophilized, live

3. Administration Route

Subcutaneous injection

4. Main components

- Live attenuated Japanese encephalitis virus at strain cultured in primary hamster kidney cells

5. Indication

Prevention of Japanese encephalitis and stillbirth due to Japanese encephalitis virus in swine.

6. Dosage, direction for use and route

Dissolve the lyophilized vaccine with the accompanying diluent. Subcutaneously inject one mL of it into pigs. It is preferable to inject subcutaneously twice at one month intervals in piglets younger than four months.

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: 10 mL (for 10 doses) per one vial

The lyophilized vaccine is yellowish gray white to white substance. When it is reconstituted with the accompanying diluent and shaken, it turns into a red orange transparent solution.

The diluent is red orange transparent solution, and its pH is 6.8 to 7.4.

8. Name and address of manufacturer

Nisseiken Co., Ltd.

9-2221-1 shin-machi, Ome, Tokyo 198-0024, JAPAN

All information are as of February, 2023