

#### STATMENT OF THE ACTIVE SUB-STANCE(S) AND OTHER INGREDIENTS: Each dose contains:

Active substance:

- A minimum of 10<sup>60</sup> EID<sub>50</sub> of freeze-dried live attenuated Newcastle Disease Virus (NDV) vaccine prepared from a reference strain La Sota.
- Other ingredients: Lactose and nonfat dried milk powder.

#### INDICATIONS:

Jovac NDV La Sota is indicated for prevention of Newcastle disease in poultry.

## CONTRAINDICATIONS:

Do not vaccinate sick or stressed birds.

## ADVERSE REACTIONS:

Rare: slight respiratory symptoms which disapears within few days. If you notice any side effects inform your veterinarian.

# TARGET SPECIES:

Poultry.

#### DOSAGE:

#### Vaccination schedule:

- 1 dose/bird.
- Booster vaccination of 2-3 weeks old birds with Jovac NDV La Sota.
  Birds should receive primary vaccination with Jovac NDV Clone or Jovac NDV B1.
- Endemic areas with Newcastle disease, birds are re-vaccinated every month.

Intraocular / intranasal route:

- Dissolve the vaccine in physiological saline solution (30 ml).
- Administer one drop of the vaccine using a dropper into one eye or nostril.
- Use the vaccine immediately after reconstitution (within two hours in cool conditions).

Oral route via drinking water:

- Reconstitute the vaccine with cool pure drinking water, free of antiseptics, adding to it nonfat dried milk powder (2 g/L) to stabilize the vaccine's activity.
- The drinking water temperature containing the vaccine must not exceed 15°C to 20°C.
- It is advisable to deprive the birds of water 1-2 hours prior to vaccination.
- The vaccine should be given in the early morning or the cool period on a hot day.
- The vaccine should be diluted in adequate quantity of final drinking water in order be consumed within one to two hours after dissolving the vaccine in water according



# Jovac NDV La Sota®

Lyophilisate live attenuated Newcastle Disease Virus strain La Sota Vaccine

to age of the birds and climatic conditions as follows: 2-3 weeks of age Dilute 1000 doses in 10 liters 7 weeks of age Dilute 1000 doses in 20 liters 14 weeks of age and older

Dilute 1000 doses in 40 liters

#### Aerogenic route by aerosol /spraying.

- Spray the vaccine solution over the birds, at a distance of 30 to 40 cm, using a coarse sprayer.
- Close windows, fans, heaters and lights while spraying and re-open after 10 minutes of spraying.
- The necessary quantity of water (distilled water) per 1000 doses are as follows: weeks of age 300 ml 4 weeks of age 400 ml Adult birds 500 ml

#### ADVICE ON CORRECT ADMINISTRATION:

- Apply usual aseptic procedures.
- Use only clean, antiseptic or disinfectant-free materials for the preparation of the vaccine solution.
- For Oral route deprive birds of drinking water 1-2 hours before vaccination.
- The vaccine should be administered to the birds within 2 hours period after reconstitution.

# WITHDRAWAL PERIOD:

# Zero days.

# SPECIAL STORAGE PRECAUTIONS:

- Store in a refrigerator (2°C-8°C)
- Protect from direct sunlight.
- Keep out of the reach and sight of children.
- The vaccine remains stable for 2 years from production date stated on the label under the recommended storage conditions.
- shelf life after reconstitution: Use the vaccine within 2 hours after reconstitution.

#### SPECIAL WARNING(S):

Special warnings for each target species: Vaccinate healthy birds only.

Special precautions for use in animals: Not applicable.

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

If the vaccine accidentally contacts eyes of the operator, medical attention is required.

Use during lay and fertility:

Can be administered during the laying period.

# MANUFATURING AUTHARIZATION HOLDER AND MANUFACTURED BY:

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#### 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. A decision to use this vaccine before and after any other veterinary medicinal product therefore needs to be made on a case-bcase basis.

# Overdose:

10 X of the dose of a vaccine: slight respiratory symptoms which disapears within few days. If you notice any side effects inform your veterinarian.

#### SPECIAL PRECAUTIONS FOR DISPOSAL:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements

#### OTHER INFORMATION:

Newcastle disease is considered as one of the most important diseases in poultry. Control of the disease can be achieved by live vaccination to prevent against mortality and morbidity and to establish local and systemic immunity.

#### Package sizes:

Vials of: 200 doses, 500 doses, 1000 doses, 2500 doses and 5000 doses.

# FOR VETERINARY USE ONLY.

02INE021.05 20/05/2021

