

# Gallovac 9R®

Lyophilisate suspension for injection live attenuated Salmonella gallinarum strain 9R vaccine

#### STATMENT OF THE ACTIVE SUB-STANCE(S) AND OTHER INGREDIENTS: Each (0.2 ml) contains:

- Active substance: Each dose contains a minimum of 2.0 x 10° CFU of freeze-dried live attenuated Salmonella gallinarum vaccine prepared from the reference strain 9R.
- Other ingredients: Bovine serum, sucrose and Sodium glutamate.

#### INDICATIONS:

For active immunization of layers and breeders chickens against Salmonella gallinarum (fowl typhoid) / pullorum and partial control of Salmonella Enteritidis infections.

#### CONTRAINDICATIONS:

Do not vaccinate sick or stressed birds.

#### ADVERSE REACTIONS:

Very rare: small nodular reactions may occur at the sight of inoculation which disappear later.

If you notice any side effects please inform your veterinarian.

#### TARGET SPECIES:

Chickens.

#### DOSAGE:

- Dosage is 0.2 ml per bird subcutaneously into the lower part in the back of the neck.
- Primary vaccination: at 6-8 weeks of age.
- Secondary vaccination: at 14-16 weeks of age.

### ADVICE ON CORRECT ADMINISTRATION:

- Apply usual aseptic procedures.
- Use only clean, antiseptic or disinfectant free materials for the preparation of the vaccine solution.
- Dissolve the freeze-dried pellet vaccine with cold and sterile solvent provided.
- Use 100 ml diluent for each 500 doses vaccine vial and 200 ml solvent for 1000 doses vaccine vial.

- Add approximately 3 ml of the solvent to the freeze-dried vaccine aseptically using a sterile syringe and mix well. Withdraw the dissolved vaccine into the syringe and add it to the solvent bottle.
- · Use the vaccine immediately after
- reconstitution (within two hours in cool conditions).
- Exposure to infection should be avoided for 14 days following vaccination to allow immunity to be developed.

#### WITHDRWAL PERIOD:

Zero days.

#### SPECIAL STORAGE PRECAUTIONS:

- Store in a refrigerator (2°C-8°C).
- Do not freeze.
- Protect from direct sunlight.Keep out of the reach and sight of
- The vaccine remains stable for 18 months 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:

Although Gallovac 9R vaccine is not pathogenic for humans; care should be taken to avoid accidental injection.

Should accidental injection occur immediate medical care should be sought.

#### Use during lay, fertility:

Do not vaccinate layers and breeders before two weeks and during laying period. can be administered during the laying period in high risk-areas.

Interaction with other medicinal products and other forms of interaction:
Do not use antibiotics or other antibacterial substances for 7 days before vaccination.

#### Overdose:

10 X of the dose of a vaccine: Rare: small nodular reactions may occur at the sight of inoculation which disappear later.

If you notice any side effects please 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:

Gallovac 9R is prepared from Salmonella gallinarum strain 9R for active immunization of chickens against Salmonella gallinarum (fowl typhoid) / pullorum and partial control of Salmonella Enteritidis infections.

#### Package sizes:

Vials of: 500 doses 1000 doses.

#### FOR VETERINARY USE ONLY.



## MANUFATURING AUTHARIZATION HOLDER AND MANUFACTURED BY:

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