

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of one 1,000-dose bottle
Box of ten 1,000-dose bottles

Box of one 5,000-dose bottle
Box of twelve 5,000-dose bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmovac 440
Lyophilisate for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose:
Double-attenuated *Salmonella* Enteritidis mutant, strain 441/0141 - 8×10^8 CFU*
* CFU = Colony Forming Unit

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water

4. PACKAGE SIZE

1 x 1,000 doses
10 x 1,000 doses
1 x 5,000 doses
12 x 5,000 doses

5. TARGET SPECIES

Chickens from one day old (breeders and layers)

6. INDICATION(S)

Active immunisation against *Salmonella* Enteritidis and *Salmonella* Typhimurium.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period from last vaccination:
Meat: 6 weeks.
Eggs: After the two first vaccinations: 6 weeks.
After the third vaccination: 3 weeks.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements. Original vaccine containers and all equipment have to be disinfected after use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4160

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1,000 doses bottle 5,000 doses bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmovac 440
Lyophilisate for use in drinking water

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Salmonella Enteritidis

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1,000 doses
5,000 doses

4. ROUTE(S) OF ADMINISTRATION

In drinking water use.

5. WITHDRAWAL PERIOD(S)

Read package leaflet.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 4 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

SALMOVAC 440
Lyophilisate for use in drinking water

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Ceva Animal Health Ltd
Unit 3 Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB
United Kingdom

Manufacturer responsible for batch release:

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Ceva-Phylaxia Veterinary Biologicals Co. Ltd.
Szállás u. 5.
1107 Budapest
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Salmovac 440
Lyophilisate for use in drinking water

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One dose of vaccine contains:

Active substance:

Double-attenuated (adenine-histidine auxotrophic)

Salmonella Enteritidis mutant, strain 441/0141-8 x 10⁸ CFU*.

* CFU = Colony Forming Unit

Excipient(s): q.s. 1 dose.

Light beige to brownish light gray lyophilisate.

4. INDICATION(S)

Active immunisation of chickens to reduce colonisation, persistence and invasion of the intestinal tract and internal organs by *Salmonella* Enteritidis and *Salmonella* Typhimurium.

Onset of immunity within 6 days after first vaccination.

Duration of immunity for *Salmonella* Enteritidis is 35 weeks after second vaccination and 63 weeks after third vaccination when used according to the recommended vaccination schedule.

Duration of immunity for *Salmonella* Typhimurium is 60 weeks after third vaccination when used according to the recommended vaccination schedule.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy chickens or chickens under heavy stress conditions. Do not use in broilers.

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens from one day old (breeders and layers).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Immunisation against *Salmonella* Enteritidis

Recommended vaccination scheme for birds on farms of unknown *Salmonella* status or positive *Salmonella* Enteritidis detection:

One dose from first day of age, a second dose two weeks later and a third dose not later than three weeks before the laying period. There should be more than two weeks between the second and third administration.

Recommended vaccination scheme for birds on farms with a known history and absence of *Salmonella* Enteritidis according to routine bacteriological monitoring:

One dose from first day of age followed by a second dose two weeks later.

A greater level of protection, with regards to the duration of immunity, is observed with the 3-dose regime.

Immunisation against *Salmonella* Enteritidis and *Salmonella* Typhimurium (whatever the *Salmonella* status)

One dose from first day of age, a second dose six weeks later and a third dose around 13 weeks of age.

Administration in drinking water (oral route)

- Apply the usual aseptic precautions to all administration procedures.
- Calculate the number of vials of vaccine required to vaccinate all the birds.
- Use only clean, antiseptic and disinfectant free drinking water.

- Reconstitute the vaccine using a small volume of drinking water in the vaccine vial. Ensure the complete dissolution of the lyophilisate. Then add the reconstituted vaccine to sufficient water to be consumed within 4 hours and mix thoroughly.

9. ADVICE ON CORRECT ADMINISTRATION

The required number of doses of reconstituted vaccine is added to sufficient water that will be consumed within 4 hours.

Birds may have drinking water withdrawn for 1–2 hours before administering vaccine. As a guide, administer the vaccine in a volume of at least 2 litres of drinking water per 1,000 chickens at first vaccination and at least 5 litres of drinking water per 1,000 chickens at second vaccination two weeks later.

If a third dose is administered, use at least 10–20 litres of drinking water per 1,000 chickens. This third dose should be administered not later than three weeks before the laying period.

10. WITHDRAWAL PERIOD(S)

Meat: 6 weeks from last vaccination.
Eggs: After the two first vaccinations: 6 weeks.
After the third vaccination: 3 weeks.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle.

Shelf life after reconstitution: 4 hours

12. SPECIAL WARNING(S)

Special warnings for each target species:

- Vaccinated chickens excrete the vaccine strain up to six weeks post vaccination. The vaccine may thus spread to susceptible birds in contact with vaccinated chickens or their manure.

Special precautions for use in animals:

- The use of the vaccine in fancy breeds has not been studied.
- Due to the adenine-histidine auxotrophy of the vaccine strain, a differentiation between vaccine and field strains is possible by means of an appropriate growth test.
- The vaccine strain is among others sensitive to ampicillin, cefotaxime, chloramphenicol, ciprofloxacin, gentamycin, kanamycin, oxytetracycline, streptomycin.
- The vaccine strain is resistant to sulfamerazine alone but sensitive to sulfamerazine and trimethoprim in combination.

- The vaccine strain can also be distinguished from the field strain by molecular biology methods, such as restriction fragment polymorphism (RFLP) in pulse gel electrophoresis (PFGE).
- The vaccine strain has been shown to spread to non-target species such as calves and pigs. It persisted in these animals and was excreted over a period of 9 days in calves and 22 days in pigs and has been shown to cause a transient increase in body temperature.

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

- Use disposable gloves when reconstituting the vaccine. Wash and disinfect hands after handling vaccine.
- Do not ingest. If the vaccine has been swallowed seek medical advice. The vaccine strain is sensitive to antibiotics with the exception of sulfamerazine.
- Immunocompromised personnel should not handle vaccine or come into contact with vaccinated chickens during the period of excretion of the vaccine strain.
- The vaccine strain has been isolated from chicken litter up to 13 days after vaccination and is excreted from vaccinated chickens up to 19 days post vaccination. In studies, the vaccine strain can be found in the environment for up to 8 weeks after the 2nd vaccination and 5 weeks after the 3rd vaccination. On very rare occasions, the vaccine strain may be isolated from the environment beyond the above mentioned period.
- Personnel involved in attending vaccinated flocks should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling litter from recently vaccinated chickens. Hands should be washed and disinfected after attending vaccinated flocks.
- Appropriate veterinary and husbandry measures should be taken to avoid spread to susceptible species.

Lay:

- Not to be used within 3 weeks (after the third vaccination) or 6 weeks (after the second vaccination) before the onset of the laying and during the laying period..
- Unvaccinated birds intended for lay should not come into contact with vaccinated birds.

Interaction with other medicinal products and other forms of interaction:

- No anti-infective substances should be used within 3 days before and after immunisation with the vaccine. In case of essential administration, the vaccination of the concerned birds has to be repeated.
- No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated".
- No competitive microflora preparations should be administered concurrently with the product.

Overdose (symptoms, emergency procedures, antidotes):

- Administration of an overdose (10 doses) can occasionally result in loose faeces and in a transient weight loss without any consequences on the final performances.

Incompatibilities:

- Do not mix with any other vaccine/immunological products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Original vaccine containers (opened as well as emptied) and all equipment used for the vaccination procedure have to be disinfected after use (disinfectants - except quaternary ammonium bases - of usual working concentration).

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

Packaging:

- 1,000-dose bottle of lyophilisate: box of 1 bottle.
- 1,000-dose bottle of lyophilisate: box of 10 bottles.
- 5,000-dose bottle of lyophilisate: box of 1 bottle.
- 5,000-dose bottle of lyophilisate: box of 12 bottles.

Not all pack sizes may be marketed.

IMMUNOLOGICAL PROPERTIES

For active immunisation of chickens against *Salmonella* Enteritidis and *Salmonella* Typhimurium.

The live vaccine strain stimulates cell-mediated immunological mechanisms (as demonstrated in mice) and antibody formation in chickens against *Salmonella* Enteritidis and *Salmonella* Typhimurium. The antibody formation does not affect serological testing for *Salmonella* Gallinarum (rapid serum agglutination).

The vaccine strain is resistant to sulfamerazine. The strain has been demonstrated as genetically stable.

For veterinary use

Approved: 19/01/21

