SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SALMOVAC 440
Lyophilisate for use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of vaccine contains:

Active substance:
Double-attenuated (adenine-histidine auxotrophic)
Salmonella Enteritidis mutant, strain 441/014 1-8 x 10^8 CFU*

* CFU = Colony Forming Unit

Excipient(s): q.s. 1 dose
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water.
Light beige to brownish light gray lyophilisate.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens from one day old (breeders and layers).

4.2 Indications for use, specifying the target species

Active immunisation of chickens to reduce colonization, 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.

4.3 Contraindications

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

4.4 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.

4.5 Special precautions for use

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 trimethoprime 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 third 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or 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.

4.8 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 of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

No competitive microflora preparations should be administered concurrently with the product.

4.9 Amounts to be administered and administration route

In drinking water use.

- 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.

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

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

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live bacterial vaccines. Salmonella.
ATCvet code: QI01AE01

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium chloride
Sodium hydroxide
Acetic acid
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after reconstitution according to directions: 4 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Nature of primary packaging elements:
Injection vial, glass type I (1000 vaccine doses).
Injection vial, glass type II (5000 vaccine doses).

Closure for freeze-dried products and caps in compliance with Ph. Eur.

Packaging:
Box with 10 bottles of lyophilisate (1000 doses)
Box with 1 bottle of lyophilisate (5000 doses)
Box with 12 bottles of lyophilisate (5000 doses)

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

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

7. MARKETING AUTHORISATION HOLDER

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 26750/4010

9. DATE OF FIRST AUTHORISATION

09 February 2016

10. DATE OF REVISION OF THE TEXT

February 2016

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of the product is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use the product must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

Approved: 09/02/2016