SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovivac S suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substances:

Inactivated cells of *Salmonella dublin* strain S342/70	1 x 10^9 cells
Inactivated cells of *Salmonella typhimurium* strain S341/70	1 x 10^9 cells

Adjuvant:

Aluminium hydroxide gel	200 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Tris buffer	
Maleic acid	
Sodium chloride	
Formaldehyde	
Thiomersal	0.13 mg
Water for injections	

Opaque fluid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the active immunisation of cattle in order to induce serological and colostral antibody production against *Salmonella dublin* and *Salmonella typhimurium* and in the face of an outbreak to reduce *Salmonella typhimurium* infections when used under field conditions as part of an overall herd management programme.

This product may also contribute to reducing *S. typhimurium* contamination of the environment.

Specific experimental data to quantify the duration of immunity, the effectiveness of a single dose re- vaccination or the degree of protection from colostral antibodies has not been generated.

Significant levels of immunity cannot be expected until two weeks after the second dose of the primary vaccination course.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
All stock showing overt clinical signs of salmonellosis at the time of the initial vaccination programme should receive appropriate treatment and be fully vaccinated once they have recovered. Any unvaccinated stock must be managed separately to vaccinated stock, with no contact between the groups. Hygiene precautions must be instituted, where possible, to prevent transfer of infection from one group to another.

All animals of a herd should be vaccinated.

The effect of maternally derived antibodies has not been studied, but it is likely that high levels of maternally derived antibodies may interfere with the development of active immunity in calves.

When vaccinating animals, stress should be avoided, particularly during pregnancy.

A small number of individuals may fail to respond to vaccination as a result of immunological incompetence or for some other reason. In the face of an outbreak of disease, it is therefore important to avoid vaccination of animals which have overt clinical salmonellosis or intercurrent disease or which have a poor nutritional status. Such animals must be isolated and treated as appropriate and then vaccinated upon clinical recovery.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction.

[1] Typically, the swellings may be warm when compared with the surrounding area for up to 5 days after vaccination. Maximum size is reached within 1-6 days after vaccination. Complete resolution or reduction to clinically insignificant reactions within 2-3 weeks after vaccination. Swellings may be painful on palpation for 1-2 days after vaccination, which will not require veterinary intervention.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Limited laboratory and field data suggest that vaccination with this product has no adverse effect on pregnancy and calving.

Fertility:
The effect of this product administered around service/insemination has not been studied.

3.8 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. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this 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.

3.9 Administration routes and dosage

Vaccination dosage
Calves up to 6 months of age: 2 ml
Adult cattle: 5 ml

Route of administration
Subcutaneous injection preferably in the loose skin on the side of the neck, observing aseptic precautions.

The use of automatic vaccination equipment is recommended.

The vaccine may be administered using a sterile needle and syringe, providing a fresh sterile needle is used each time the rubber cap is punctured, to avoid contamination of the remaining contents.

Primary vaccination course
Where diagnosis of salmonellosis caused by *S. dublin* and/or *S. typhimurium* has been confirmed, all at risk adult cattle, including lactating cows, dry cows, heifers, barren cows and in-contact bulls (but excluding any with overt clinical signs of salmonellosis), should receive two 5 ml injections separated by an interval of 21 days.
For pregnant cows, this primary vaccination course can be given irrespective of the reproductive status. Any pregnant cows that have not calved within 8 weeks of the second dose of vaccine should receive a further 5 ml dose of this product 3-4 weeks pre-calving.
Healthy calves from approximately 3 weeks of age may also be given a primary vaccination course.
Calves should be given two 2 ml injections separated by an interval of 14 to 21 days.

Re-vaccination scheme
All cattle vaccinated with the primary vaccination course of this product should receive a 5 ml injection at least two weeks prior to each period of risk or at intervals of not more than 12 months thereafter.
As part of an overall herd management programme, for pregnant cattle, it is advised that for each subsequent pregnancy, in order to maintain a sufficient level of active immunisation to reduce *S. dublin* and *S. typhimurium* infections under field conditions, a single injection of 5 ml should be administered approximately 3-4 weeks before calving.
The efficacy of this product has been established in the field using the recommended programme of use. No specific experimental data are available in support of the effectiveness of a single dose re- vaccination.

The use of automatic vaccination equipment is recommended. Use a vaccinator with vented draw-off spike or similar device only.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Accidental overdose is very unlikely to cause any reaction other than described in point “Adverse events”, although the swelling may be larger and, together with the associated signs, may last slightly longer. A slightly reduced body weight gain was noticed in some calves that received an overdose. No adverse local or systemic reactions were noted in overdose studies performed in pregnant cows and calves.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AB05.

To stimulate active immunity against *Salmonella dublin* and *Salmonella typhimurium* infections.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf life after first opening the immediate packaging: use within 10 hours.
Partially used containers must be discarded at the end of each day's operation.

5.3 Special precautions for storage

Store in a refrigerator (2 ℃– 8 ℃). Do not freeze. Protect from light.

5.4 Nature and composition of immediate packaging

Polyethylene multidose bottles (50 ml) with rubber stoppers sealed with an aluminium crimp cap

Pack size: Cardboard box containing 1 bottle of 50 ml.

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

Medicines should not be disposed of via wastewater.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 01708/3018

8. DATE OF FIRST AUTHORISATION

10 August 1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

January 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall
Approved: 08 January 2025