

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovivac S

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Formalin killed cells of <i>Salmonella dublin</i> strain S342/70	1 x 10 ⁹ cells
Formalin killed cells of <i>Salmonella typhimurium</i> strain S341/70	1 x 10 ⁹ cells

Adjuvant:

Aluminium hydroxide gel	200 mg
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Excipients:

The vaccine contains thiomersal as a preservative.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the 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. Bovilis Bovivac S may also contribute to reducing *S. typhimurium* contamination of the environment.

Specific experimental data to quantify the duration of immunity 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.

4.3 Contraindications

None.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

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.

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.

4.6 Adverse reactions (frequency and seriousness)

Swellings at the injection site may occur. Typically, these swellings may be warm when compared to the surrounding area for up to 5 days after vaccination, reach a maximum size within 1-6 days after vaccination and completely disappear or reduce to clinically insignificant reactions within 2-3 weeks after vaccination. In addition, swellings may be slightly painful on palpation for 1-2 days after vaccination, although this will not require veterinary intervention.

Occasional hypersensitivity reactions may occur.

4.7 Use during pregnancy, lactation or lay

When vaccinating animals, stress should be avoided, particularly during pregnancy. The effect of Bovilis Bovivac S administered around service/insemination has not been studied. Limited laboratory and field data suggest that vaccination with Bovilis Bovivac S has no adverse effect on pregnancy and calving.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product.

4.9 Amounts to be administered and administration route

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 Bovilis Bovivac S 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 Bovilis Bovivac S 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 Bovilis Bovivac S 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.

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

Accidental overdose is very unlikely to cause any reaction other than described in point 'Adverse reactions', 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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: inactivated bacterial vaccine.
ATC vet code: QI02AB05.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tris
Maleic acid
Sodium chloride
Formaldehyde
Thiomersal
Purified water

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf life

24 months.
Once opened, use of the vaccine must be completed within 10 hours. Partially used containers must be discarded at the end of each day's operation.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

6.5 Nature and composition of immediate packaging

Polyethylene multidose bottles (50 ml) with rubber stoppers sealed with an aluminium crimp cap. The containers and closures comply with the Ph. Eur.

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

Any unused product or waste materials should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4415

9. DATE OF FIRST AUTHORISATION

10 August 1999

10. DATE OF REVISION OF THE TEXT

February 2021

Approved: 10/02/21

