LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovivac S

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substances:

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

Adjuvant:

Aluminium hydroxide gel	200 mg

The vaccine contains thiomersal as a preservative.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

For cattle

6. INDICATION(S)

[not required to be mentioned according to Art 58 of Directive 2001/82/EC as amended, furthermore it would require too much space on the packaging]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Route: subcutaneous injection.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

[None.]

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. Protect from light.

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4415

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE

50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovivac S

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:
Active substances:
Formalin killed cells of *Salmonella dublin* and *Salmonella typhimurium*1 x 10^9 cells per strain.

3. PHARMACEUTICAL FORM

Suspension for injection
Read the package leaflet before use.

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

50 ml

5. TARGET SPECIES

For cattle

6. ROUTE(S) OF ADMINISTRATION

Route: SC injection.

7. WITHDRAWAL PERIOD

Withdrawal period: zero days.

8. BATCH NUMBER

BN: {number}

9. EXPIRY DATE

EXP: {month/year}
Once broached, use within 10 hours.

10. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

11. NAME OF THE MARKETING AUTHORISATION HOLDER

{MSD Animal Health logo}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bovilis Bovivac S

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

Marketing Authorisation Holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer for batch release[1]:
Intervet International B.V.
5831 AN Boxmeer

MSD Animal Health UK Limited
Milton Keynes, Bucks MK7 7AJ, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovivac S

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

Bovilis Bovivac S is a suspension for injection containing inactivated cells of *Salmonella dublin,* strain S342/70 (1 x 10^9 cells/ml) and inactivated cells of *Salmonella typhimurium,* strain S341/70 (1 x 10^9 cells/ml). Bovilis Bovivac S contains aluminium hydroxide as an adjuvant and thiomersal as a preservative.

4. INDICATION(S)

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.

[1] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

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

Route and method of administration
Subcutaneous injection preferably in the loose skin on the side of the neck, observing aseptic precautions. Shake the vaccine bottle before use.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store in a refrigerator. Do not freeze. Protect from light.
Do not use after the expiry date stated on the label.
Once broached/opened, use within 10 hours. Partially used containers must be discarded at the end of each day's operations.

12. SPECIAL WARNING(S)

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.

Significant levels of immunity cannot be expected until two weeks after the second dose of the primary vaccination course.
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.
The efficacy of Bovilis Bovivac S has been established in the field using the recommended programme of use.
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.

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.

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.

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

Do not mix with any other vaccine or immunological product.

There are no special warning applicable to people administrating the vaccine.

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

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

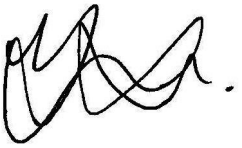
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

For animal treatment only.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 27 January 2021