LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovivac S suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/3018

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PET vial 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovivac S suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml contains:
Inactivated cells of *Salmonella dublin* and *Salmonella typhimurium* 1 x 10^9 cells per strain

50 ml

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp.{mm/yyyy}
Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bovilis Bovivac S suspension for injection for cattle

2. 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

Excipient:

Thiomersal	0.13 mg

Opaque fluid.

3. Target species

Cattle.

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.
The efficacy of this product has been established in the field using the recommended programme of use.

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.

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 S administered around service/insemination has not been studied.

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 vaccine 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

Overdose:
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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes 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 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.

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 periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 ℃ – 8 ℃). Do not freeze. Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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 operations.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/3018

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

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release[1]:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

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

Contact details to report suspected adverse reactions:
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24, Ireland

17. Other information

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

Gavin Hall
Approved: 08 January 2025