PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON
100 ml, 50 ml, 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Leptavoid-H
Suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
2 – 3 x 10^9 inactivated *Leptospira interrogans* serovar Hardjo 204 organisms;
0.5 – 0.7 mg alum, equivalent to aluminium (adjuvant);
0.085 mg – 0.115 mg thiomersal (preservative).

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

20 ml
50 ml
100 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the active immunisation of cattle from 1 month of age against *Leptospira interrogans* serovar Hardjo and *Leptospira borgpetersenii* serovar Hardjo.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: Subcutaneous injection.
2 ml per dose
For complete indications, dosage and administration, warnings, precautions and disposal advice:

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

For complete indications, dosage and administration, warnings, precautions and disposal advice: **Read package leaflet before use**.

10. EXPIRY DATE

EXP end of: {month/year}

Once opened, use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze. Protect from light.
Keep the container in the outer carton.

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

For complete indications, dosage and administration, warnings, precautions and disposal advice: **Read package leaflet before use**.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-VPS
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach 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 01708/4568

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL
100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Leptavoid-H
Suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
2 – 3 x 10^9 inactivated *Leptospira interrogans* serovar Hardjo 204 organisms;
0.5 – 0.7 mg alum, equivalent to aluminium (adjuvant);
0.085 mg – 0.115 mg thiomersal (preservative).

3. PHARMACEUTICAL FORM

Suspension for injection for cattle

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the active immunisation of cattle from 1 month of age against *Leptospira interrogans* serovar Hardjo and *Leptospira borgpetersenii* serovar Hardjo.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: Subcutaneous injection.
For complete indications, dosage and administration, warnings, precautions and disposal advice: **Read package leaflet before use.**

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

For complete indications, dosage and administration, warnings, precautions and disposal advice: **Read package leaflet before use.**

10. EXPIRY DATE

EXP end of: {month/year}

Once opened, use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze. Protect from light.

Keep the container in the outer carton.

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

For complete indications, dosage and administration, warnings, precautions and disposal advice: **Read package leaflet before use.**

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-VPS
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach 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 01708/4568

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL
50 ml, 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Leptavoid-H
Suspension for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

2 – 3 x 10^9 inact. *Leptospira interrogans* serovar Hardjo 204 per ml.

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

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

Route: SC injection.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP end of: {month/year}

Once opened, use within 8 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

POM-VPS Vm 01708/4568

Keep the container in the outer carton.

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

PACKAGE LEAFLET FOR:
Bovilis Leptavoid-H
Suspension for injection for cattle

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 responsible for batch release:
Burgwedel Biotech GmbH
Im Langen Felde 5
30938 Burgwedel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Leptavoid-H Suspension for injection for cattle

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

Each ml contains:
2 – 3 x 10^9 inactivated *Leptospira interrogans* serovar Hardjo 204 organisms, 0.5 – 0.7 mg alum, equivalent to aluminium (adjuvant) and 0.085 mg – 0.115 mg thiomersal (preservative).

Aqueous fluid with precipitate that re-suspends on shaking.

4. INDICATION(S)

For the active immunization of cattle from 1 month of age against *Leptospira interrogans* serovar Hardjo and *Leptospira borgpetersenii* serovar Hardjo.
To reduce shedding of *L. interrogans* serovar Hardjo in urine.
To improve herd fertility when infertility is diagnosed as caused by *Leptospira* Hardjo.
Circulating antibody is detectable 14 days following the first injection and persists for 12 months following completion of the primary course.
Conjunctival challenge demonstrates 12 months cross protection against *L. borgpetersenii* serovar Hardjo (subtype Hardjobovis).

In addition to circulating antibody response, vaccination with Bovilis Leptavoid-H also stimulates cell-mediated immunity to *L. borgpetersenii* serovar Hardjo which is maintained for at least five months and responds in the event of a challenge five months post vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A transient rise in temperature of 1 – 1.3 °C lasting 24 – 48 hours after vaccination may occur, particularly after the second dose. This reaction is very common.
Administration of the first and second dose may produce swellings in most animals with diameters of up to 7.5 and 8.5 cm respectively. These local reactions normally resolve over several weeks after administration, but may persist for longer in a small number of animals. Local reactions are very common.
Occasional hypersensitivity reactions may occur. In the case of hypersensitivity the use of adrenaline or other appropriate treatment is recommended.

Youngstock vaccination: The sizes of the reactions seen in the second primary course may be larger than those seen in the first primary course (up to 17 cm after 5 vaccinations 28 days apart). There may also be an increased sensitivity at the injection site compared to the primary vaccination. Animals may also exhibit a transient rise in temperature of 1.2 - 2.6 °C following the second primary course (see dosing recommendations).

A greater proportion of animals may show a transient rise in temperature of 1 – 2 °C lasting 24 – 48 hours after an overdose administration. Injection site swellings are similar to those seen with a single dose.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

7. TARGET SPECIES

Cattle.

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

Minimum age of administration: 1 month.
Dose: 2 ml.
Route of administration: Subcutaneous injection.

Vaccination regime
Primary course
The primary course consists of two doses with an interval of at least 4 weeks and not more than 6 weeks between them. Ideally the course should be completed in the spring before the main season of transmission of *Leptospira* Hardjo.

Re-vaccination
Re-vaccination with a single dose should be given annually to maintain protection against infection and progressively reduce exposure in the herd.
If the primary course is given later than the spring, the first booster should be given in the following spring and annually thereafter.

Youngstock vaccination
If the calves are inoculated before 5 months of age, a further primary course should be given at that age (allowing an interval of 4 weeks between vaccinations), to avoid interference from maternally derived antibodies with the immune response.
Older calves not immediately exposed to infection can be given the initial course at any time, but it is advisable to complete vaccination shortly before the main season of transmission of leptospirosis.

To improve herd fertility
For maximum benefit the primary course should be completed within 12 months of infertility being diagnosed as caused by *Leptospira* Hardjo.

9. ADVICE ON CORRECT ADMINISTRATION

The container should be well shaken to re-suspend the precipitate before doses are withdrawn.

The vaccine should be deposited beneath the skin covering the chest wall, well behind the shoulder, or beneath the skin covering the side of the neck.

Use a draw-off needle in the vial stopper to avoid excess broaching of the stopper. Syringes and needles should be sterilised before use and the injection made subcutaneously through an area of clean, dry skin taking precautions against contamination. Exercise care with part used containers and discard all part used containers within 8 hours of opening to reduce the potential for contamination.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
Keep the container in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after 'EXP end of'.
Shelf-life after first opening the container: 8 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species

Vaccinated cattle may be positive for diagnostic tests and therefore unacceptable for export to some countries.

Special precautions for use in animals

The vaccine should not be administered within two weeks of breeding as this may reduce conception rates. This may be due to handling stress rather than a specific vaccine effect. Such effects are transient, are unlikely to be above 10% and are minor when compared with the potential overall increase in conception rates demonstrated in *Leptospira* Hardjo infected herds. However, it should be considered when timing AI especially with valuable semen.
Maternally derived antibody may interfere with the performance of the vaccine in young animals. Refer to appropriate dosing recommendations above in section 8.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical advice immediately and show the package leaflet or the label to the physician.
Even though animals may have been vaccinated it should be remembered that no vaccine is 100% effective and that the risk, albeit very much reduced, of transmission of leptospirosis from cattle to their handlers, remains. Appropriate precautions should be maintained at all times and prompt medical advice sought in the event of clinical signs of possible infection.

Pregnancy and fertility

Can be used during pregnancy but should not be administered within two weeks of breeding.

Also see section ‘Special precautions for use in animals’ above.

Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered to animals of 8 months of age or older on the same day, with Bovilis BVD vaccine.
The two vaccines should be administered at separate sites. For the concurrent use of Bovilis Leptavoid-H and Bovilis BVD vaccines in naïve animals, the primary vaccination course must be completed at least 4 weeks before the expected gestation, in order that foetal protection can be established.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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 (symptoms, emergency procedures, antidotes)

A greater proportion of animals may show a transient rise in temperature of 1 – 2 °C lasting 24 – 48 hours after an overdose administration.
Injection site swellings are similar to those seen with a single dose.

Incompatibilities

Do not mix with any other veterinary medicinal product.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2021.

15. OTHER INFORMATION

For animal treatment only.

ATCvet code: QI02AB03.
To stimulate active immunity against *Leptospira interrogans* serovar Hardjo and *L. borgpetersenii* serovar Hardjo.

Pack sizes

Carton with 1 x 20 ml (10 doses) glass vial.
Carton with 1 x 50 ml (25 doses) flexible low density polyethylene bottle.
Carton with 1 x 20 ml (10 doses), 1 x 50 ml (25 doses) or 1 x 100 ml (50 doses) PET vial.

Not all pack sizes may be marketed.

POM-VPS
To be supplied only on veterinary prescription.

Vm 01708/4568

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

Approved 19 November 2021