SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Leptavoid-H Suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

per ml	
Inactivated *Leptospira interrogans* serovar Hardjo 204 organisms	2 – 3 x 10^9
Adjuvant	
Alum, equivalent to aluminium	0.5 - 0.7 mg
Excipients	
Thiomersal (preservative)	0.085 - 0.115 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
Aqueous fluid with precipitate that re-suspends on shaking.

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the active immunisation of cattle from 1 month of age against *Leptospira interrogans* serovar Hardjo and *Leptospira borgpetersenii* serovar Hardjo.
To reduce shedding of *Leptospira 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 *Leptospira borgpetersenii* serovar Hardjo subtype Hardjobovis.
In addition to the circulating antibody response, vaccination with Bovilis Leptavoid-H also stimulates cell-mediated immunity to *Leptospira*

borgpetersenii serovar Hardjo which is maintained for at least five months and responds in the event of a challenge five months post vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

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 A.I. especially with valuable semen.

Maternally derived antibody may interfere with the performance of the vaccine in young animals. Refer to section 4.9 for appropriate dosing recommendations.

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.

4.6 Adverse reactions (frequency and seriousness)

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 8.5cm 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 section 4.9 for dosing recommendations.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions 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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy but should not be administered within two weeks of breeding (see section 4.5).

4.8 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 month 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.

4.9 Amounts to be administered and administration route

Minimum age of administration: 1 month.

Dose: 2 ml.
Route of administration: Subcutaneous injection.

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.

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. Use a draw-off needle in the vial stopper to avoid excess broaching of the stopper.

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), as otherwise maternally derived antibodies may interfere 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.

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

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.

4.11 Withdrawal Period(s)

Zero days.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for bovidae; inactivated bacterial vaccines; leptospira. ATCvet code: QI02AB03

To stimulate active immunity against *Leptospira interrogans* serovar Hardjo and *Leptospira borgpetersenii* serovar Hardjo.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Alum
Formaldehyde
Sodium chloride

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after opening the immediate packaging: 8 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Glass Type I (Ph. Eur.) vial closed with chlorobutyl rubber stopper type I (Ph. Eur.) and aluminium seal: 20 ml (10 doses).
Flexible low density polyethylene (Ph. Eur.) bottle closed with chlorobutyl rubber stopper type I (Ph. Eur.) and aluminium seal: 50 ml (25 doses).
Polyethylene terephthalate (PET) vials closed with nitrile rubber stopper type I (Ph. Eur.) and aluminium seal: 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses).

Pack sizes: 1 x 20 ml (10 doses), 1 x 50 ml (25 doses) or 1 x 100 ml (50 doses).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4112

9. DATE OF THE FIRST AUTHORISATION

24 October 2005

10. DATE OF REVISION OF THE TEXT

November 2024

Approved 18 November 2024
Gavin Hall