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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioBos L(6), suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition of 1 dose (2 ml):

Active substances:

Leptospira pomona inact.	min. titre 16 determined by ALR*
Leptospira hardjo type *hardjo-prajitno* inact.	min. titre 35 determined by ALR*
Leptospira hardjo type *hardjo-bovis* inact.	min. titre 32 determined by ALR*
Leptospira grippotyphosa inact.	min. titre 64 determined by ALR*
Leptospira icterohaemorrhagiae inact.	min. titre 81 determined by ALR*
Leptospira canicola inact.	min. titre 35 determined by ALR*

* The values were determined on the basis of the titres of the reference serum obtained from 5 rabbits vaccinated with a batch compliant with the challenge potency test on the target species (ALR = agglutination-lytic reaction).

Adjuvants:

Aluminium hydroxide hydrated 2%	7.5 mg

Excipients:

Thiomersal	0.2 mg
Formaldehyde	max. 0.19%

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

Whitish to pinkish milky fluid, divided at longer standing into white sediment and almost clear supernatant.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For the active immunisation of cattle from 4 weeks of age against leptospirosis (6 serovares contained in the vaccine) to prevent infection, foetal infection and Leptospira excretion, mainly in the urine.

Onset of immunity: 4 weeks after basic vaccination (i.e. after administration of the first 2 doses)
Duration of immunity: 12 months after basic immunisation.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The effect of maternal antibodies on the vaccine efficacy has not been tested.

4.5 Special precautions for use

Special precautions for use in animals

A gradual resorption of injected antigen depot takes place in the injection site. The depot will disappear spontaneously within 21 days after vaccination. At inspection of the meat of animals slaughtered within 21 days after vaccination this altered tissue must be removed.

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Symptomatic treatment is recommended in singular cases of anaphylactic reaction.

Adequate local reactions - oedema up to 20 mm in diameter, can be expected after vaccination, which is resorbed spontaneously within three weeks after vaccination.

The frequency of these adverse reactions is characterised as uncommon according to the following rules:

- very common (adverse reactions occurred in more than 1 in 10 animals in the course of one treatment)
- common (more than 1 but less than 10 in 100 animals)
- uncommon (more than 1 but less than 10 in 1,000 animals)
- rare (more than 1 but less than 10 in 10,000 animals)
- very rare (less than 1 in 10,000 animals, including isolated reports)

4.7 Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when administered concurrently with other veterinary medicinal products. Decision about using this vaccine before or after any other veterinary medicinal product must be based on consideration of individual cases.

4.9 Amounts to be administered and administration route

Dose - **2 ml subcutaneously** behind the shoulder blade, regardless of the age of animals (calves from 4 weeks of age, heifers and cows).

Before use the vaccine must be heated to a temperature between 15°C and 25°C and the contents of the vial should be shaken well.

a) Primary vaccination

Basic immunisation - requires the administration of two vaccine doses at an interval of 4-6 weeks, the second dose should be administered not later than 4 weeks prior to mating. The main effect is prevention of Leptospira excretion in the urine.

If the second vaccine dose is administered not later than 2 weeks before mating, there is also a significant prevention of foetal infection.

Calves can be vaccinated from 4 weeks of age, using the basic immunisation (i.e. administration of two doses). Heifers are vaccinated once before mating.

b) After basic vaccination (i.e. after administration of the first 2 doses):

To maintain protective immunity, annual revaccination with one dose, administered not later than 2 weeks prior to mating, is necessary.

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

No other adverse reactions than those described in section 4.6 were observed after administration of a double dose of the vaccine to the target species.

4.11 Withdrawal periods

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Immunologicals for cattle, inactivated bacterial vaccines.

ATCvet code: *QI02AB03*
For the stimulation of the active immunity against leptospirosis (*L. pomona, L. hardjo* type *hardjo-prajitno, L. hardjo* type *hardjo-bovis, L. grippotyphosa, L. icterohaemorrhagiae* and *L. canicola*)

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrated aluminium hydroxide for adsorption
Thiomersal
Formaldehyde
Sodium chloride
Potassium dihydrogen phosphate
Potassium hydrogen phosphate dodecahydrate
Water for injection

6.2 Incompatibilities

Do not mix with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening of package: 10 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2°C – 8°C).
Protect from frost.
Protect from light.
Store in a dry place.

6.5 Nature and composition of immediate packaging

The vaccine is filled into glass vials of hydrolytic class I and II and into plastic vials sealed with pierceable rubber stoppers and secured with aluminium caps. The outer package is a paper box or a plastic box.

Pack size:

1×10 ml, 10×10 ml of the product	10 ml glass vials of hydrolytic class I
1×50 ml of the product	50 ml glass vials of hydrolytic class II
1×100 ml of the product	100 ml glass vials of hydrolytic class II
1×100 ml of the product	120 ml plastic vials

Not all pack sizes may be marketed.
An approved package leaflet is enclosed in each package.

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

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

7. MARKETING AUTHORISATION HOLDER

Bioveta, a.s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic
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8. MARKETING AUTHORISATION NUMBER
96/021/11-C

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
04/04/2011

10. DATE OF REVISION OF THE TEXT
09/2015

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

OTHER INFORMATION
Veterinary medicinal product subject to prescription.