

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Lepto 2 suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:

Inactivated *Leptospira interrogans* serogroup Canicola, serovar Portland-vere, strain Ca-12-000: 990 – 1755 Units*

Inactivated *Leptospira interrogans* serogroup Icterohaemorrhagiae, serovar Copenhageni, strain 820K: 699 – 1277 Units*

* Antigenic mass ELISA Units.

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

Colourless suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For active immunisation of dogs to reduce infection with *Leptospira interrogans* serogroup Canicola and *Leptospira interrogans* serogroup Icterohaemorrhagiae.

Specific claims:

The duration of immunity induced by the vaccine was established as at least one year. Nobivac Lepto 2 significantly reduces the number of animals which develop a urinary tract infection which can predispose to development of a carrier condition after *L. Canicola* and *L. Icterohaemorrhagiae* infection.

4.3 Contraindications

None.

4.4 Specific warnings for each target species

Vaccinate healthy animals only.

The vaccine may not be effective in dogs incubating the disease at the time of vaccination.

Animals that have received the corresponding anti-serum or immunosuppressive drugs should not be vaccinated until an interval of at least 4 weeks has elapsed.

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.

Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A transient rise in body temperature post-vaccination has been observed in rare cases during the clinical safety studies.

Dogs may show local reactions after injection in very rare cases, according to spontaneous pharmacovigilance reports. A diffuse swelling, up to 5 cm in diameter, may be observed at the site of injection for up to 4 days. Occasionally this swelling may be hard and painful, but this will diminish gradually and disappear after 2 – 3 weeks.

A transient acute hypersensitivity reaction - with signs that may include lethargy, facial oedema, pruritus, vomiting or diarrhoea - may occur shortly after vaccination in very rare cases. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening with additional signs like dyspnoea or collapse. If such reactions occur appropriate treatment is recommended.

Mild systemic signs such as lethargy and anorexia were reported very rarely.

Clinical signs of immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia, or immune-mediated polyarthritis have been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
in 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy and lactation

Can be used during pregnancy.

The vaccine has been shown to be safe for use in pregnant bitches which have previously been vaccinated with Nobivac Lepto 2.

4.8 Interactions with other medicaments and forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with live vaccines in the Nobivac range containing canine distemper virus (strain Onderstepoort), canine adenovirus type 2 (strain Manhattan LPV3), canine parvovirus (strain 154) and/or canine parainfluenza virus (strain Cornell) components authorised for subcutaneous administration.

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Nobivac Rabies, the inactivated rabies (strain Pasteur RIV) vaccine in the Nobivac range.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products 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

Subcutaneous use.

Administer 1 dose (1 ml) per animal.

Allow the vaccine to reach room temperature (15 °C – 25 °C) before use.
Sterile injection equipment should be used.

Primary vaccination course:

All dogs not previously vaccinated should be vaccinated twice 2 – 4 weeks apart.
Puppies should be at least 6 weeks of age before they receive the first vaccination.

Revaccination

A single annual booster dose is recommended.

Nobivac Lepto 2 may be used to reconstitute Nobivac DHPPi, DHP, Pi or Parvo-C as indicated in the appropriate package leaflets.

For more detailed advice on vaccination programmes and how the product may be used in conjunction with other Nobivac dog vaccines under specific circumstances, contact the company/distributor or refer to the support literature.

4.10 Overdose (symptoms, emergency procedures, antidotes)

No symptoms other than at single dose (see section 4.6).

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Canidae*, Inactivated bacterial vaccine.
ATCvet code: QI07AB01

Strains of *Leptospira interrogans* serogroups Canicola and Icterohaemorrhagiae are responsible for leptospirosis in dogs. The active ingredients of the vaccine *Leptospira interrogans* Canicola, strain Ca-12-000 and *Leptospira interrogans* Icterohaemorrhagiae, strain 820K stimulate active immunity against these serogroups.

6. PHARMACEUTICAL PRECAUTIONS

6.1 List of excipients

Sodium chloride
Potassium chloride
Sodium-L-lactic acid
Calcium chloride
Water for injection

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except the vaccines mentioned in section 4.8 where their combined use is authorised.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months.
Shelf-life after first opening the container: use immediately.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Store in the original package.
Protect from light.

6.5 Nature and composition of immediate packaging

Type I glass vial(s) of 1 ml closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Pack sizes

Plastic box with 10 or 50 vials of 1 ml (1 dose).
Cardboard box with 1, 10 or 50 vials of 1 ml (1 dose).
may be marketed.

6.6 Special precautions for the disposal of unused product or waste material derived from the use of such product

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4360

9. DATE OF FIRST AUTHORISATION

31 May 2002

10. DATE OF REVISION OF THE TEXT

July 2021

Approved: 21/07/21

D. Austin