

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Lepto 2 Suspension for Injection for Dogs

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

### **Active substances:**

Inactivated *Leptospira interrogans* serogroups:

- Canicola; serovar Portland-verre, strain Ca-12-000  $\geq 990$  Units/ml\*
- Icterohaemorrhagiae; serovar Copenhageni, strain 820K  $\geq 699$  Units/ml\*

\* Antigen mass ELISA Units

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 from 6 weeks of age to reduce infection with *Leptospira interrogans* serogroup Canicola and *Leptospira interrogans* serogroup Icterohaemorrhagiae.

The product significantly reduces the number of animals which develop a urinary tract infection which can predispose to development of a carrier condition after *L. interrogans* serogroup Canicola and *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni infection.

Duration of immunity: at least one year.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

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

Only healthy dogs should be vaccinated.

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

In the case of accidental self-injection, encourage bleeding, then disinfect the site.

If symptoms develop, seek medical attention and show a copy of the package leaflet to the physician.

#### **4.6 Adverse reactions (frequency and seriousness)**

A local reaction (diffuse swelling) may occur in up to 10 % vaccinates for up to three days after vaccination.

In the rare event of a hypersensitivity reaction following vaccination, administer an antihistamine, corticosteroid or adrenaline, without delay and by the most immediate route.

#### **4.7 Use during pregnancy, lactation or lay**

The vaccine has been shown to be safe for use in pregnant bitches which have previously been vaccinated with the product.

#### **4.8 Interaction with other medicinal products and other forms of interactions**

Safety and/or efficacy data are available which demonstrate that this vaccine can be mixed with live vaccines from 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).

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.

Antiserum and immunosuppressive drugs may reduce the response to vaccination.

#### **4.9 Amounts to be administered and administration route**

Administer 1 ml of vaccine by subcutaneous injection.

Allow the vaccine to reach room temperature (15 – 25 °C) before use.

Sterile injection equipment should be used.

#### **Vaccination regimen**

##### *Primary 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.

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

None other than those mentioned in section 4.6.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Inactivated bacterial vaccine; *Leptospira*

ATC vet code: Q107AB01

Strains of *Leptospira interrogans* serogroups Canicola and Icterohaemorrhagiae are responsible for leptospirosis in dogs. The active ingredients of the vaccine stimulate active immunity against these strains.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium chloride  
Potassium chloride  
L-Lactic acid sodium salt  
Calcium chloride  
Water for injection

### **6.2 Major incompatibilities**

Do not mix with any other veterinary medicinal product, except those listed in section 4.8.

### **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:

Cardboard or plastic box with 10 or 50 vials of 1 ml (1 dose).

Not all pack sizes may be marketed.

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

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**

Intervet Ireland Limited  
Magna Drive  
Magna Business Park, Citywest Road  
Dublin 24  
Ireland

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA10996/169/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 3 March 2004  
Date of last renewal: 2 March 2009

**10 DATE OF REVISION OF THE TEXT**

June 2021