1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Spirovac

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) of Spirovac contains the following:

Active substances:
Inactivated *Leptospira borgpetersenii*serovar Hardjo **≥2RP***
*** RP = ELISA Relative Potency**.

Adjuvant
Aluminium hydroxide3.0 to 3.6 mg of aluminium

Excipients
Formaldehyde<1 mg
Thiomersalmax 0.01% (w/v)

See Section 6.1 for full list of excipients.

3 PHARMACEUTICAL FORM

Suspension for injection. Slightly coloured turbid liquid which might contain a loose sediment.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle from 4 weeks of age.

4.2 Indications for use, specifying the target species

For active immunisation

- of cattle to reduce kidney colonisation and shedding of *Leptospira borgpetersenii* serovar Hardjo type hardjobovis to the extent that no viable organisms can be detected by culture in the urine of vaccinated animals after challenge; a 3 weeks onset of immunity and 12 months duration of protection have been demonstrated by challenge with *Leptospira borgpetersenii* serovar Hardjo type hardjobovis.

- of cattle persistently infected with *Leptospira borgpetersenii* serovar Hardjo type hardjobovis: to reduce urinary shedding of *Leptospira borgpetersenii* serovar Hardjo type hardjobovis withoutclearance of renal colonisation; this effect appears 4 weeks post vaccination and its duration is unknown.The epidemiological significance of the

reduced shedding has not been demonstrated.

The vaccination may not prevent abortion in cows in which placental infection has already occurred.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Even though animals may have been vaccinated, the risk of transmission of leptospirosis from cattle to their handlers, albeit very much reduced, 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 diffuse and oedematous swelling up to 10 cm in diameter, sometimes sensitive to palpation, could occur in up to 40% of animals and can last for up to 66 days after completion of vaccination. The reaction to subsequent vaccinations and the reaction in pregnant animals (see 4.7) are more marked. The injection site reaction may be sensitive to palpation the week following vaccination and may persist as a hard nodule for several weeks.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.The swelling is more marked in pregnant animals. A diffuse swelling of up to 22 cm in diameter can occur following second injection. This effect is more marked for pregnant animals in their third trimester of pregnancy.

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 used with any other veterinary medicinal product. 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

Dose: 2 ml

Administration:
By subcutaneous injection, preferably in the neck. Shake the container well before withdrawing the dose.
Basic vaccination scheme:
2 doses of vaccine separated by a 4 to 6 week interval.
Revaccination scheme:
A single 2 ml dose on an annual basis.

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

No adverse drug reactions, other than those listed in Section 4.6, occurred after administration of twice the normal dose.As part of the natural response following vaccination, and following an overdose of twice the maximum dose of the vaccine, a reactive lymphadenopathy in the local lymph node as well as production of a subcutaneous, granulomatous, inflammatory reaction could be visible under the skin for at least 2 months. The total duration of this reaction in the underlying tissues is not known.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate an active immunity against *Leptospira borgpetersenii*serovar Hardjo type hardjobovis.

Vaccination induces humoral antibody response and cell-mediated immunity as measured by serology and gamma-interferon production.A marked, statistically significant difference is also seen in the anamnestic response following a single booster vaccination or infection (challenge) 12 months after primary vaccination.

A strong serological cross-reactivity post vaccination has been demonstrated against *Leptospira interrogans*serovar Hardjo, a closely related species in the same serovar. This was sustained for at least 12 months following primary vaccination, and is also seen in the anamnestic response following a single booster vaccination. A cattle challenge model is not available to document protection.

ATC Vet code: QI02AB03 (Immunologicals for bovidae, inactivated bacterial vaccines, Leptospira).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Thiomersal
Formaldehyde
Water for injections

6.2 Incompatibilities

Do not mix with any veterinary medicinal product.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Container: 5 doses (10ml) or 25 doses (50ml) Glass type I vials.
Closure:Chlorobutyl stopper with aluminium overseal.
Outer Packaging:Cardboard carton with package insert leaflet.
Pack sizes:5 or 25 doses (10 or 50ml).
Not all pack sizes may be marketed.

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

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

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/065/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 28th October 2011

10 DATE OF REVISION OF THE TEXT

September 2017