SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spirovac suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

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

Adjuvant:
Aluminium hydroxide 3.0 to 3.6 mg of aluminium

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Aluminium hydroxide	<1 mg
Thiomersal	max 0.01% (w/v)
Formaldehyde	
Water for injections	

Slightly coloured turbid liquid which might contain a loose sediment.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For active immunisation of cattle from 4 weeks of age 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.

Onset of immunity: 3 weeks.

Duration of immunity: 12 months (demonstrated by challenge with *Leptospira borgpetersenii* serovar Hardjo type hardjobovis).

For active immunisation of cattle from 4 weeks of age persistently infected with *Leptospira borgpetersenii* serovar Hardjo type hardjobovis: to reduce urinary shedding of *Leptospira borgpetersenii* serovar Hardjo type hardjobovis without clearance of renal colonisation. The epidemiological significance of the reduced shedding has not been demonstrated.

Onset of immunity: 4 weeks.
Duration of immunity: unknown.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
The vaccination may not prevent abortion is cows in which placental infection has already occurred.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccinated cattle may be positive in diagnostic tests for leptospirosis and therefore unacceptable for export to some countries.

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.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1] Injection site nodule[2]

[1]Diffuse and oedematous, up to 10 cm in diameter which can last for up to 66 days. May be sensitive to palpation the week following vaccination. The swelling is more marked in

pregnant animals, particularly in their third trimester of pregnancy, and can be up to 22 cm in diameter following second injection.
[2]May persist for several weeks.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

Dose: 2 ml.

Administration route:
Subcutaneous injection, preferably in the neck. Shake the container well before withdrawing the dose.

Vaccination scheme:

Basic vaccination scheme:
2 doses of vaccine separated by a 4 to 6 week interval, from 4 weeks of age.

Revaccination scheme:
A single 2 ml dose on an annual basis.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events, other than those listed in Section 3.6, 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.

In repeated dosing studies when an additional fourth injection was given shortly after the recommended vaccination regime, all animals showed sensitivity to palpation and a

swelling at the injection site that lasted for several days. In all cases, the injection site will persist as a hard nodule, which may be detectable for several months.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AB03

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Container:	5 doses (10 ml) or 25 doses (50 ml) 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 50 ml).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBERS

Vm 42058/5149
Vm 42058/3042

8. DATE OF FIRST AUTHORISATION

27 October 2005

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Gavin Hall

Approved: 23 January 2025