

PARTICULARS TO APPEAR ON THE OUTER PACKAGE – CARDBOARD BOX
(1 x 5 or 25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spirovac suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Inactivated *Leptospira borgpetersenii* serovar Hardjo \geq 2RP.

3. PACKAGE SIZE

5 doses

25 doses

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 60021/3062

15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGING UNITS –
LABEL ON GLASS VIAL – 5 or 25 doses**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spirovac



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Leptospira borgpetersenii serovar Hardjo

5 doses

25 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 10 hours.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Spirovac

2. Composition

Each 2 ml dose contains:

Active substance:

Inactivated *Leptospira borgpetersenii* serovar Hardjo type hardjobovis $\geq 2\text{RP}^*$

* RP = ELISA Relative Potency.

Adjuvant:

Aluminium hydroxide 3.0 to 3.6 mg of aluminium

Excipients:

Formaldehyde <1 mg

Thiomersal max 0.01% w/v

Slightly coloured turbid liquid which might contain a loose sediment.

3. Target species

Cattle.

4. Indications for use

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 colonization. The epidemiological significance of the reduced shedding has not been demonstrated.

Onset of immunity: 4 weeks.

Duration of immunity: unknown.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

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

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.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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.

Overdose:

No adverse events, other than those listed in Section "Adverse events", 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.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle:

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

²May persist for several weeks.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Dose: 2 ml.

Administration route: Subcutaneous injection, preferably in the neck.

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.

9. Advice on correct administration

Shake the container well before withdrawing the dose.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2°C - 8°C).
Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 10 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 60021/3062

Cardboard box with 1 vial of 5 doses (10 ml).

Cardboard box with 1 vial of 25 doses (50 ml).

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

Manufacturer responsible for batch release:

Zoetis Belgium
Rue Laid Burniat, 1
1348 Louvain-La-Neuve
Belgium

17. Other information

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.

POM-VPS	Veterinary medicinal product subject to prescription
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Gavin Hall

Approved: 26 February 2025