PARTICULARS TO APPEAR ON THE OUTER PACKAGE - BOX
Spirovac – 1 x 5 or 25 dose box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spirovac

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (2 ml) contains

Inactivated *Leptospira borgpetersenii* serovar Hardjo	**≥2RP***

*** RP = ELISA Relative Potency**

Adjuvant Aluminium hydroxide	3.0 to 3.6 mg of aluminium
Formaldehyde	<1 mg
Thiomersal	max 0.01% (w/v)
Water for injections	Ad 2ml

3. PHARMACEUTICAL FORM

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

4. PACKAGE SIZE

1 x 5 or 25 dose vial (10 or 50ml).

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For active immunisation of cattle to reduce kidney colonisation and shedding of *Leptospira borgpetersenii* serovar Hardjo in urine.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Two doses of vaccine 4 to 6 week apart. Subcutaneous injection. Single booster vaccination every 12 months.

8. WITHDRAWAL PERIOD

Zero Days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry Date
Once opened, use within 10 hours

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. POM- VPS

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4134

17. MANUFACTURER'S BATCH NUMBER

Lot No.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - LABEL
Spirovac – 5 or 25 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spirovac

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated *Leptospira borgpetersenii* serovar Hardjo ≥ 2RP

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 or 25 doses.

4. ROUTE(S) OF ADMINISTRATION
5. WITHDRAWAL PERIOD

Zero Days

6. BATCH NUMBER

Lot No.:

7. EXPIRY DATE

Expiry Date:
Once opened, use within 10 hours

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PACKAGE LEAFLET

Spirovac
Spirobac (Belgium)
Spirovac Lepto (France)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer for the batch release:
Zoetis Belgium SA
Rue Laid Burniat, 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

A suspension for injection containing per 2 ml dose inactivated *Leptospira borgpetersenii* serovar Hardjo type hardjobovis vaccine (**≥2RP***) the adjuvant aluminium hydroxide (3.0 to 3.6 mg of aluminium) and the excipients formaldehyde (<1mg) and thiomersal (max 0.01% w/v).
*** RP = ELISA Relative Potency**

4. INDICATION(S)

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 without clearance 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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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 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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.
Do not mix with any other veterinary medicinal product.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL WARNING(S)

For animal treatment only.

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.

As part of the natural response following vaccination, and following an overdose of twice the maximum dose of the product, 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.

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.
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.

Do not mix with any other veterinary medicinal product.

Withdrawal period: zero days.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2013

15. OTHER INFORMATION

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.

Approved 12 December 2019