ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Piro lyophilisate and solvent for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 1 ml dose:

Active substance:
606 (301-911) total antigenic mass units of soluble parasite antigen (SPA) from *Babesia canis* and *Babesia rossi* cultures

Adjuvant (in the solvent)
250 (225-275) µg saponin

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For active immunisation of dogs of 6 months of age or older against *Babesia canis* to reduce the severity of clinical signs associated with acute Babesiosis (*B. canis*) and anaemia as measured by Packed Cell Volume (PCV).

Onset of immunity: Three weeks after the basic vaccination course.

Duration of immunity: 6 months after the last (re-)vaccination.

4.3 Contra-indications

See section 4.7.

4.4 Special warnings for each target species

Only healthy dogs should be vaccinated. In particular, chronic asymptomatic carriers should be identified and treated before vaccination, with substances that do not compromise immunological responsiveness.

It is recommended that vaccinations are given at least one month before the tick season.

As active babesia infection might interfere with the development of protective immunity, it is recommended to reduce exposure to ticks during the period of vaccination.

Currently there is only evidence of the efficacy of the vaccine against challenge with *B. canis*. There is a possibility that vaccinated dogs facing a challenge with other babesia's may develop disease and require treatment.

Vaccination with Nobivac Piro does not prevent infection. As a consequence a milder form of disease caused by *B. canis* can occur. If mild babesia-like symptoms arise, which last for more than 2 days, veterinary advice should be sought.

4.5 Special precautions for use

Special precautions for use in animals

Ensure that the lyophilisate is completely reconstituted before use.

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

In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Commonly reported post-vaccination reactions are a diffuse swelling and/or hardened nodule, accompanied by pain, at the site of vaccination. In general this disappears within 4 days. In rare cases, the reactions after the second dose of vaccine may remain for 14 days. In addition, systemic signs, such as lethargy and a reduction in appetite may also commonly occur, sometimes accompanied by pyrexia and a stiff gait. These reactions should disappear within 2-3 days.

4.7 Use during pregnancy and lactation

Do not use in pregnant or lactating bitches.

4.8 Interactions 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 medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Vaccination scheme:
Basic vaccination course: First injection from 6 months of age, second injection 3 to 6 weeks later.
Revaccination: Single dose, every 6 months after the last (re-)vaccination.

Allow the solvent to reach room temperature (15 - 25°C). Aseptically add the solvent to the lyophilisate. Allow the lyophilisate to dissolve completely. **DO NOT SHAKE,** but swirl gently. Withdraw the entire contents of the reconstituted vaccine into a sterile syringe and administer the whole contents subcutaneously.

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

No adverse reactions other than those mentioned in section 4.6. were observed after the administration of an overdose of vaccine.

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against babesiosis caused by *Babesia canis*.

ATC vet code: QI07AO

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine: culture medium
Solvent: sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, water for injection.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the product.

6.3 Shelf life

Lyophilisate: 57 months (4 years and 9 months)
Solvent: 2 years
Reconstituted product should be used immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2°C - 8°C). Protect from light.

6.5 Nature and composition of immediate packaging

For the lyophilisate and the solvent: 3-ml vials of glass Type I closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Pack sizes:
Cardboard box containing 1 vial of lyophilisate and 1 vial of solvent.
Cardboard box containing 5 vials of lyophilisate and 5 vials of solvent.
Cardboard box containing 10 vials of lyophilisate and 10 vials of solvent.

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 materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN Boxmeer

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/046/001-003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation: 2 September 2004

10 DATE OF REVISION OF THE TEXT

16 July 2009

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

D. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substance(s)

Intervet de Bilt
Ambachtstraat 2, De Bilt
The Netherlands

Intervet International B.V.
Wim de Korverstraat 35, Boxmeer
The Netherlands

Name and address of the manufacturer responsible for batch release

Intervet International B.V.
Wim de Korverstraat 35, Boxmeer
The Netherlands

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to medical prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

D. STATEMENT OF THE MRLs

Not applicable

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

Outer box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Piro

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE(S)

Per dose:
606 (301-911) total antigenic mass units of soluble parasite antigen (SPA) from *Babesia canis* and *Babesia rossi* cultures

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

1 x 1 dose
5 x 1 dose
10 x 1 dose

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Vaccine against Babesia canis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

S.C. injection

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

See Package Insert

10. EXPIRY DATE

Exp: {date}

11. SPECIAL STORAGE CONDITIONS

Store and transport at 2 - 8°C. Protect from light.
Reconstituted vaccine should be used immediately.

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

Disposal: see package insert

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

For animal treatment only.
Veterinary medicinal product subject to prescription.

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

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
NL - 5831 AN Boxmeer

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/046/001-003

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON SMALL SINGLE DOSE CONTAINERS OTHER THAN AMPOULES

MINIMUM PARTICULARS TO APPEAR ON AMPOULES

Label of the vaccine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Piro

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 dose: 606 (301-911)units *Babesia* antigens

3. ROUTE(S) OF ADMINISTRATION

S.C.

4. BATCH NUMBER

Lot: {number}

5. EXPIRY DATE

Exp: {date}

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON SMALL SINGLE DOSE CONTAINERS OTHER THAN AMPOULES

MINIMUM PARTICULARS TO APPEAR ON AMPOULES

Label of the adjuvant

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adjuvated solvent for Nobivac Piro.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Not applicable.

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

Not applicable.

5. BATCH NUMBER

Lot: {number}

6. EXPIRY DATE

Exp: {date}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN Boxmeer

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Piro lyophilisate and solvent for suspension for injections for dogs

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

Per 1 ml dose of the reconstituted product:
606 (301-911) total antigenic mass units of soluble parasite antigen (SPA) from *Babesia canis* and *Babesia rossi* cultures
Adjuvant: 250 (225-275) µg saponin (from the solvent)

4. INDICATION(S)

For active immunisation of dogs of 6 months of age or older against *Babesia canis* to reduce the severity of clinical signs associated with acute Babesiosis (*B. canis*) and anaemia as measured by Packed Cell Volume (PCV).
Onset of immunity: Three weeks after the basic vaccination course.
Duration of immunity: 6 months after the last (re-)vaccination .

5. CONTRAINDICATIONS

Do not use in pregnant or lactating bitches.

6. ADVERSE REACTIONS

Commonly reported post-vaccination reactions are a diffuse swelling and/or hardened nodule, accompanied by pain, at the site of vaccination. In general this disappears within 4 days. In rare cases, the reactions after the second dose of vaccine may remain for 14 days. In addition, systemic signs, such as lethargy and a reduction in appetite may also commonly occur, sometimes accompanied by pyrexia and a stiff gait. These reactions should disappear within 2-3 days.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

1 ml reconstituted vaccine, via subcutaneous injection.

Vaccination scheme:
Basic vaccination course: First injection from 6 months of age, second injection 3-6 weeks later.
Revaccination: Single dose, every six months after the last (re-) vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the solvent to reach room temperature (15 - 25°C). Aseptically add the solvent to the lyophilisate. **DO NOT SHAKE**, but swirl gently.
Make sure that the lyophilisate is completely dissolved before use
Withdraw the entire contents of the reconstituted vaccine into a sterile syringe and administer the whole contents subcutaneously.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE CONDITIONS, IF ANY

Store and transport refrigerated (2°C - 8°C). Protect from light.
Keep out of reach and sight of children.
Do not use after the expiry date which is stated on the label.

12. SPECIAL WARNINGS

Only healthy dogs should be vaccinated. In particular, chronic asymptomatic carriers should be identified and treated before vaccination, with substances that do not compromise immunological responsiveness.

It is recommended that vaccinations are given at least one month before the tick season.

As active Babesia infection might interfere with the development of protective immunity it is recommended to reduce exposure to ticks during the period of vaccination.

Currently there is only evidence of the efficacy of the vaccine against challenge with *B. canis*. There is a possibility that vaccinated dogs facing a challenge with other babesia's may develop disease and require treatment.

Vaccination with Nobivac Piro does not prevent infection. As a consequence a milder form of disease caused by *B. canis* can occur. If mild babesia-like symptoms arise which last for more than 2 days veterinary advice should be sought.

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.

In the absence of compatibility studies, do not mix with any other veterinary medicinal product except the solvent supplied for use with the vaccine.

In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

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 the local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

16 July 2009

15. OTHER INFORMATION

Pack sizes:
Cardboard box containing 1 vial of lyophilisate and 1 vial of solvent.
Cardboard box containing 5 vials of lyophilisate and 5 vials of solvent.
Cardboard box containing 10 vials of lyophilisate and 10 vials of solvent.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

For animal treatment only.