I. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Rabies

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active components:
Rabies strain Pasteur RIV; at least 2 I.U. per dose

Preservative:
Thiomersal 0.01%

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats, cattle, sheep, goats, foxes, ferrets and horses.

4.2 Indications for use specifying the target species (if appropriate)

For the active immunisation of healthy dogs, cats, cattle, sheep, goats, ferrets, foxes and horses, and in principle all healthy mammals against rabies.

4.3 Contraindications

None

4.4 Special warnings

None

4.5 Special precautions for use

Allow the vaccine to reach ambient temperature (15-25°C) before use.
Use sterile injection equipment.
Shake before and during use.

Special precautions for use in animals

Vaccinate healthy animals only.

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

None

4.6 Adverse reactions (frequency and seriousness)

After subcutaneous administration occasionally a transient palpable nodule may occur at the site of injection.

Generalised hypersensitivity reactions following administration may occasionally occur.

4.7 Use during pregnancy and lactation

Can be used during pregnancy in dogs.

4.8 Interaction with other medicinal products and other forms of interaction

Nobivac Rabies can be used to reconstitute the freeze-dried canine vaccines of the Nobivac series.
Nobivac Rabies can be administered with the Nobivac leptospirosis vaccines at the same time but at a different administration site.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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

1 ml by subcutaneous or intramuscular injection.

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

After subcutaneous administration occasionally a transient palpable nodule may occur at the site of injection.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Inactivated viral vaccine
ATC vet code for dogs: QI07AA02
Induction of active immunity against rabies.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

Do not mix with any other veterinary medicinal product except the vaccines of the Nobivac series mentioned in section 4.8.

6.2 Shelf life

At least 4 years at 2-8°C.

Broached vials of the 10-dose presentation should be used within one working day.

6.3 Special precautions for storage

Store at 2° - 8°C.
Do not freeze.
Protect from light.

6.4 Nature and composition of immediate packaging

Glass vials closed with a rubber stopper, and sealed with an aluminium cap.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
Boxmeer – The Netherlands

ANNEX A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac® Rabies

2. PACKAGE SIZE

10x1 dose
50x1 dose
10x10 doses

3. INDICATION(S)

Inactivated vaccine containing ≥ 2 I.U. rabies virus strain Pasteur RIV per dose. Preservative: Thiomersal 0.01%.

4. EXPIRY DATE

Expiry {month/year}
Mfg.date {month/year}

5. SPECIAL STORAGE CONDITIONS

Store at 2° - 8°C.
Do not freeze.
Protect from light.

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

For animal treatment only.

7. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Boxmeer – The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac® Rabies

2. INDICATION(S)

Inactivated rabies vaccine

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

1 dose
10 doses

4. SPECIAL STORAGE CONDITIONS

Store between 2° - 8°C.
Do not freeze.
Protect from light.

5. BATCH NUMBER

Batch {number}

6. EXPIRY DATE

Expiry {month/year}
Mfg.date {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

ANNEX B. PACKAGE LEAFLET

Nobivac® Rabies

FOR ANIMAL TREATMENT ONLY

DESCRIPTION

This vaccine contains an inactivated culture of rabies virus, cloned out of strain Pasteur RIV with a potency of ≥ 2 I.U. The virus is grown on the BHK-21 clone CT cell line and inactivated with beta-propiolactone. It is presented as an aluminium phosphate adsorbed vaccine.

COMPOSITION

Active components:
Rabies strain Pasteur RIV: at least 2 I.U. per dose.
Preservative: Thiomersal 0.01%

INDICATION

For the active immunisation of healthy dogs, cats, cattle, sheep, goats, ferrets, foxes and horses, and in principle all healthy mammals against rabies.

DOSAGE AND ADMINISTRATION

1 ml by subcutaneous or intramuscular injection.

RECOMMENDED VACCINATION PROGRAMME

	Dogs/Cats	Cattle/Horses	Ferrets
Primary vaccination at an age of more than	3 months*	6 months*	3 months*
Revaccination every	3 years**	2 years**	1 year**
Route of administration	i.m. or s.c.	i.m.	s.c.

* Primary vaccination can be administered at an earlier age, but then a repeat vaccination must be given at the age of 3 or 6 months depending on the species.
** Recommended revaccination interval is based upon results from challenge experiments. Local regulations in force may require earlier revaccination.

Results from serological investigations indicate that vaccination of **sheep**, **goats**, and **foxes** provides protection for at least one year.

VACCINATION REACTIONS

After subcutaneous administration occasionally a transient palpable nodule may occur at the site of injection.

NOTE
- Vaccinate healthy animals only.
- Generalised hypersensitivity reactions following administration may occasionally occur.
- Allow the vaccine to reach ambient temperature (15-25°C) before use.
- Use sterile injection equipment.
- Shake before and during use.
- Nobivac Rabies can be used to reconstitute the freeze-dried canine vaccines of the Nobivac series.
- Nobivac Rabies can be administered with the Nobivac leptospirosis vaccines at the same time but at a different administration site.
- Keep out of the reach and sight of children.

IMMUNITY
In dogs, peak antibody titres have been demonstrated to occur by 3 weeks after vaccination.

STORAGE
Store at 2 - 8°C.
Do not freeze.
For the 10 dose presentation, broached vials should be used within one working day.

PRECAUTIONS FOR DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL
No special precautions are required.
Dispose by the appropriate channels.

PACKING
Vials containing 1 or 10 doses.

Product of:
INTERVET INTERNATIONAL B.V.
BOXMEER – THE NETHERLANDS