PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobivac Ducat**,** lyophilisate and solvent for suspension for injection, for cats.

2. Composition

Each dose (1 ml) of reconstituted vaccine contains:
Active substances:
Live attenuated feline rhinotracheitis virus, strain G2620A $\geq 10^{4.8}$ $TCID_{50}$[1],
Live attenuated feline calicivirus, strain F9 $\geq 10^{4.6}$ PFU[2].
[1]$TCID_{50}$: Tissue Culture Infectious Dose 50%
[2]PFU: Plaque Forming Units

Lyophilisate: off-white pellet. Solvent: clear colourless solution.

3. Target species

Cats.

4. Indications for use

Active immunisation of cats to reduce the clinical signs caused by infection with feline rhinotracheitis virus and feline calicivirus infections.
Onset of immunity: 4 weeks. Duration of immunity: 1 year.

5. Contraindications

See section “Pregnancy and lactation” under “Special warnings”.

6. Special warnings

Vaccination at six weeks of age has been proven to be safe. Vaccinate only healthy animals.

Special precautions for safe use in the target species:
Care should be taken that aerosol is not formed when vaccinating the cat as nasal or oral exposure could result in clinical respiratory signs including lethargy and malaise. For the same reason, the cat should be prevented from licking the injection site.

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 leaflet or the label to the physician.

Pregnancy and lactation:
Do not use during pregnancy or lactation, as the product has not been tested in pregnant or lactating queens.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other, except the vaccine in the Nobivac range containing rabies antigen, strain Pasteur RIV, where this product and the combined use is authorised. 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:
In the case of an overdose, a transient swelling (≤ 5 mm) at the injection site may occur for four to ten days. A transient increase in temperature (< 40.8 °C) may occur while occasionally lethargy for one day after vaccination may be observed.

Major incompatibilities:
Do not mix with any other vaccine or immunological product except the solvent supplied with the product or with the vaccine in the Nobivac range containing rabies antigen, strain Pasteur RIV (where this product and the combined use is authorised).

7. Adverse events

Cats:

Very common (>1 animal / 10 animals treated):	Injection site swelling.[1]
Common (1 to 10 animals / 100 animals treated):	Elevated temperature.[2]
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reactions (e.g. pruritus, dyspnoea, vomiting, diarrhoea and collapse including anaphylaxis).[3] Lethargy.[4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain.[1] Febrile limping syndrome reactions in kittens.[5]

[1] A local swelling (≤ 5 mm), sometimes painful, may be observed at the injection site for one day post-vaccination.
[2] Elevated body temperature (up to 40 °C) may occur for 1-2 days post vaccination.
[3] Sometimes fatal. If such a reaction occurs, appropriate treatment should be administered without delay.
[4] Lethargy may be observed during the first day after vaccination.
[5] As reported in the literature, febrile limping syndrome reactions in kittens may occur after the use of any vaccine containing a feline calicivirus component.

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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

Primary vaccination: Cats from 8 weeks of age onwards should receive two vaccinations with an interval of 3-4 weeks. Revaccination: Annual booster.
During the initial vaccination course, the vaccine in the Nobivac range containing rabies antigen, strain Pasteur RIV, may be used to reconstitute this vaccine at the vaccination at 12 weeks of age (where this product and the combined use is authorised).

9. Advice on correct administration

Allow the sterile solvent provided to reach room temperature. Aseptically reconstitute the lyophilised vaccine with one ml of the solvent. Shake well after addition of the solvent. One ml of the reconstituted vaccine should be given by subcutaneous injection.

Visual appearance of the reconstituted product: off-pink or pink coloured suspension.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Lyophilisate: Store in a refrigerator (2 °C – 8 °C). Protect from light.
Solvent: can be kept below 25 °C if stored separately from the lyophilisate. Do not freeze.
Shelf life after reconstitution according to directions: 30 minutes.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after 'Exp.'. The expiry date refers to the last day of that month.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{To be completed nationally}

Cardboard or plastic box containing: 5 x 1 dose, 10 x 1 dose, 25 x 1 dose or 50 x 1 dose of lyophilisate and solvent. Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}. Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary)*.

16. Contact details

Marketing authorisation holder:
{to be completed nationally}

Manufacturer responsible for batch release: Intervet International B.V., Wim de Körverstraat 35, NL-5831 AN Boxmeer

Contact details to report suspected adverse reactions:
{to be completed nationally}

17. Other information

{To be completed nationally where applicable}

Any additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation and in accordance with article 14(2) and/or national requirements may appear in this rectangle boxed area