SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) of reconstituted vaccine contains:

Active substances:
Live attenuated feline calicivirus, strain F9: $\geq 10^{4.6}$ PFU[2];
Live attenuated feline rhinotracheitis virus, strain G2620A: $\geq 10^{4.8}$ $TCID_{50}$[1].

[1]$TCID_{50}$: Tissue Culture Infectious Dose 50%
[2]PFU: Plaque-Forming Units

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

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

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

Active immunisation of cats to reduce the clinical signs caused by infection with feline rhinotracheitis virus (FVR) and feline calicivirus (FCV) infections.

Onset of immunity: 4 weeks.
Duration of immunity: 1 year.

4.3 Contraindications

See section 4.7.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals:
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.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amount(s) to be administered and administration route

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.

Vaccination schedule:
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 the vaccine at the vaccination at 12 weeks of age (where this product and the combined use is authorised).

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

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.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccines
ATCvet code: QI06AD03

To stimulate active immunity against feline rhinotracheitis virus and feline calicivirus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Disodium phosphate dihydrate
Hydrolysed gelatin
Sucrose

Solvent:
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 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).

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
Lyophilisate: 2 years
Solvent: 5 years.

Shelf-life after reconstitution according to directions: 30 minutes

6.4 Special precautions for storage

Lyophilisate: Store in a refrigerator (2 °C – 8 °C). Protect from light.
Solvent: Can be stored below 25 °C if stored separately from the lyophilisate.
Do not freeze.

6.5 Nature and composition of immediate packaging

Lyophilisate: 1 dose vial of glass type I (Ph. Eur.) closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.
Solvent: 1 dose vial of glass type I (Ph. Eur.) closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Pack sizes:
Cardboard or plastic boxes with 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.

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

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirement.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5013

9. DATE OF FIRST AUTHORISATION

18 October 2004

10. DATE OF REVISION OF THE TEXT

November 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Gavin Hall

Approved 14 November 2024