SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Tricat Trio, 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[1];
Live attenuated feline rhinotracheitis virus, strain G2620A: $\geq 10^{5.2}$ PFU[1];
Live attenuated feline panleucopenia virus, strain MW-1: $\geq 10^{4.3}$ $CCID_{50}$[2].
[1]PFU: Plaque-Forming Units
[2]$CCID_{50}$: Cell Culture Infectious Dose 50%

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 calicivirus (FCV) and rhinotracheitis virus (FVR),
- to prevent the clinical signs, leucopenia and virus excretion caused by infection with feline panleucopenia virus (FPLV).

Onset of immunity: for FCV and FVR: 4 weeks; for FPLV: 3 weeks.
Duration of immunity for FCV and FVR: 1 year, for FPLV: 3 years.

4.3 Contraindications

See section 4.7

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Maternal antibodies, which may persist up to the age of 9-12 weeks, can have a negative influence on the efficacy of vaccination. In the presence of maternal antibodies, vaccination may not completely prevent the clinical signs, leucopenia and virus excretion following an FPLV infection. In such cases where a relatively high level of maternally derived antibodies is expected, the vaccination schedule should be planned accordingly.

4.5 Special precautions for use

Special precautions for use in animals:
Not applicable.

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] Sneezing, cough, nasal discharge, dullness, decreased appetite.[2]
Common (1 to 10 animals / 100 animals treated):	Elevated temperature.[3]
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Injection site pain, injection site hair loss, injection site pruritus. Hypersensitivity reactions (e.g. pruritus, dyspnoea, vomiting, diarrhoea and collapse including anaphylaxis).[4] Febrile limping syndrome reactions in kittens.[5]

[1] Local swelling (≤ 5 mm), sometimes painful, may occur at the injection site 1 – 2 days post-vaccination.
[2] May be observed for up to 2 days post-vaccination.
[3] Elevated body temperature (up to 40 °C) may occur for 1 – 2 days post-vaccination.

[4] Sometimes fatal. If such a reaction occurs, appropriate treatment should be administered without delay.
[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 or lactation, as the product has not been tested in pregnant or lactating queens. Live FPL virus can cause reproductive problems in pregnant queens and birth defects in the progeny.

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

4.9 Amount(s) to be administered and administration route

Use 1 ml solvent to reconstitute the lyophilisate (= 1 single dose).
Visual appearance of the reconstituted product: off-pink or pink coloured suspension.
Bring the vaccine to room temperature and administer 1 ml of the vaccine per animal by subcutaneous injection.
Use sterile injection equipment, free from traces of disinfectants.

Vaccination schedule:
Primary vaccination:
Two single dose inoculations, 3 – 4 weeks apart.
The first inoculation can be given from the age of 8 – 9 weeks and the second inoculation from the age of 12 weeks. (see also section 4.4)
Revaccination:
A single dose (1 ml) according to the following schedule:
Revaccination against feline calicivirus and feline rhinotracheitis virus must be given every year (with vaccines containing the F9 and G2620 strains, where available).
Revaccination against feline panleucopenia virus can be given every three years (with strain MW-1 as in Nobivac Tricat Trio, where available).

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

At ten-fold overdose, a slight painful swelling may be observed at the injection site for 4 – 10 days.
A slight transient rise in temperature (up to 40.8 °C) may occur for 1 – 2 days.

In some cases general discomfort, coughing, sneezing, transient lethargy and reduced appetite may be observed for a few days post vaccination.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccine for cats.

ATCvet code: QI06AD04

To stimulate active immunity against feline calicivirus, feline rhinotracheitis virus and feline panleucopenia virus in cats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Disodium phosphate dihydrate
Hydrolysed gelatin
Pancreatic digest of casein
Sorbitol

Solvent:
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injection

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
Lyophilisate: 33 months.
Solvent: 5 years.
Shelf life after reconstitution according to directions: use within 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 requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5015

9. DATE OF FIRST AUTHORISATION

1 May 2007

10. DATE OF REVISION OF THE TEXT

November 2024

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