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:

Qualitative composition of excipients and other constituents
Lyophilisate:
Disodium phosphate dihydrate
Hydrolysed gelatin
Pancreatic digest of casein
Sorbitol
Solvent:
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

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

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Active immunisation of cats:
- to reduce the clinical signs caused by infection with feline calicivirus (FCV) and feline 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.

3.3 Contraindications

See section 3.7.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

3.6 Adverse events

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 section “Contact details” of the package leaflet.

3.7 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.

3.8 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.

3.9 Administration routes and dosage

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 3.4).
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).

3.10 Symptoms of overdose (and where applicable emergency procedures, and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI06AD04

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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: 30 minutes.

5.3 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.

5.4 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

7. MARKETING AUTHORISATION NUMBER

Vm 01708/3004

8. DATE OF FIRST AUTHORISATION

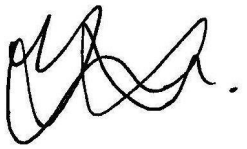
01 May 2007

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

February 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.



Approved: 23 February 2023