SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Tricat Trio, Lyophilisate and Solvent for Suspension for Injection for Cats
(AT, DE: Nobivac RCP; ES: Nobivac Tricat Novum, SE: Nobivac Tricat Novum* vet)

* The affix 'Novum' is added temporarily during transitional period between old and new product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml:

Lyophilisate
Active substances:
live attenuated feline calicivirus, strain F9: ≥4.6 $\log_{10}$ PFU[1] ;
live attenuated feline herpes virus type 1, strain G2620A: ≥5.2 $\log_{10}$ PFU[1];
live attenuated feline panleucopenia virus, strain MW-1: ≥4.3 $\log_{10}$ $CCID_{50}$ [2]

[1]PFU: Plaque-Forming Units
[2]$CCID_{50}$: Cell Culture Infective Dose 50%

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

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.
Off-white lyophilisate

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 feline herpes virus type 1 (FHV),
– to prevent the clinical signs, leucopenia and virus excretion caused by infection with feline panleucopenia virus (FPLV).
Onset of immunity: for FCV and FHV: 4 weeks; for FPLV: 3 weeks.

Duration of immunity for FCV and FHV: 1 year, for FPLV: 3 years.

4.3 Contraindications

See point 4.7

4.4 Special warnings

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

(i) Special precautions for use in animals

Only healthy animals should be vaccinated.

(ii) 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.

4.6 Adverse reactions (frequency and seriousness)

A slight painful swelling may be observed at the injection site for 1-2 days. A slight transient rise in body temperature (up to 40°C) may occur for 1-2 days. In some cases sneezing, coughing, nasal discharge, and a slight dullness or reduced appetite may be observed for up to 2 days post vaccination. In very rare cases, the vaccine may cause hypersensitivity reactions (pruritus, dyspnoea, vomiting, diarrhoea and collapse).

4.7 Use during pregnancy, lactation or lay

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 Amounts to be administered and administration route

Use 1 ml solvent to reconstitute the lyophilisate (= 1 single dose).
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:
Basic 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 herpesvirus type 1 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

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccine for cats
ATCvet-code: QI06AD04
To stimulate active immunity against feline calicivirus, feline herpesvirus type 1 (feline rhinotracheitis virus) and feline panleucopenia virus in cats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Disodium phosphate dehydrate
Hydrolized gelatine
Pancreatic digest of casein
Sorbitol

Solvent:
Disodium phosphate dehydrate
Potassium dihydrogen phosphate
Water for injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packed 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 kept 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 fraction: 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, 10, 25 or 50 doses of vaccine 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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4533

9. DATE OF FIRST AUTHORISATION

01 May 2009

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 14 August 2020