LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD OR PLASTIC BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Tricat Trio, lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose at least:
$10^{4.6}$ PFU of feline calicivirus, strain F9
$10^{5.2}$ PFU of feline rhinotracheitis virus, strain G2620A
$10^{4.3}$ $CCID_{50}$ of feline panleucopenia virus, strain MW-1

3. PACKAGE SIZE

5 x 1 dose
10 x 1 dose
25 x 1 dose
50 x 1 dose

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 30 min.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze. Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3004

15. BATCH NUMBER

Lot {number}

Under Article 13 of EU Reg 2019/6 the following additional information has been included:

Keep the vials in the outer box.

Accidental injection is dangerous.

Disposal: Read package leaflet.

To be supplied only on veterinary prescription.

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL LABEL - lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Tricat Trio

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose

Feline calicivirus, feline rhinotracheitis virus, feline panleucopenia virus.
See comment below.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 30 min.

In accordance with Article 13 of EU Reg 2019/6 the following additional information is included:

Lyophilisate for suspension for injection

SC

For animal treatment only.

Subject to available space, quantitative information will be included as follows:
Feline calicivirus ≥ $10^{4.8}$ $CCID_{50}$, feline rhinotracheitis virus ≥ $10^{4.6}$ PFU and feline panleucopenia virus ≥ $10^{4.3}$ PFU per dose

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL – solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Solvent
– sterile buffered solution

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

In accordance with Article 13 of EU Reg 2019/6 the following additional information is included:

Read the package leaflet before use.

For animal treatment only.

Store below 25 °C.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobivac Tricat Trio**,** lyophilisate and solvent for suspension for injection, for cats

2. Composition

Each dose (1 ml) of reconstituted vaccine contains:
Active substances:
Live attenuated feline calicivirus, strain F9: ≥ $10^{4.6}$ PFU[1]
Live attenuated feline rhinotracheitis virus, strain G2620A: ≥ $10^{5.2}$ PFU[1]
Live attenuated feline panleucopenia virus, strain MW-1: ≥ $10^{4.3}$ $CCID_{50}$[2]

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

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

3. Target species

Cats.

4. Indications for use

Active immunisation of cats from the age of 8 – 9 weeks onwards to reduce clinical signs caused by an infection with feline calicivirus (FCV) and feline rhinotracheitis virus (FVR) and to prevent clinical signs, virus excretion and leucopenia caused by feline panleucopenia virus (FPLV).
Onset of immunity is 4 weeks for the FCV and FVR components and 3 weeks for the FPLV component.
Duration of immunity is 1 year for the FCV and FVR components and 3 years for the FPLV component.

5. Contraindications

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

6. Special warnings

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.

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.

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.

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.

Overdose:
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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 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:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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

At least $10^{4.6}$ PFU of FCV, strain F9, $10^{5.2}$ PFU of FVR, strain G2620A and $10^{4.3}$ $CCID_{50}$ of FPLV, strain MW-1 in 1.0 ml solvent.

Primary vaccination:
Two doses injected subcutaneously, at an interval of 3 – 4 weeks, are required. The first inoculation is given from the age of 8 – 9 weeks and the second inoculation from the age of 12 weeks.

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 this vaccine, where available).

9. Advice on correct administration

Reconstitute the freeze-dried vaccine with the accompanying solvent immediately before use. Inject the solvent into the vial containing the lyophilisate and shake gently until the pellet is dissolved completely. Bring the vaccine to room temperature and administer 1 ml of vaccine by the subcutaneous route. Use sterile injection equipment but avoid contact of the vaccine with disinfectant.
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.
Keep the vials in the outer box.

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.

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.
Ask your veterinary surgeon how to dispose of medicines no longer required.
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

Marketing authorisation number:
Vm 01708/3004

Pack sizes:
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

December 2022

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

16. Contact details

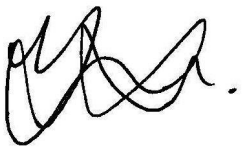
Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

17. Other information

For animal treatment only.



Approved: 23 February 2023