LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose at least:
4.6 $\log_{10}$ PFU of live att. FCV, strain F9
5.2 $\log_{10}$ PFU of live att. FVR, strain G2620A
4.3 $\log_{10}$ $CCID_{50}$ of live att. FPLV, strain MW-1

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cats

6. INDICATION(S)

Live vaccine against feline calicivirus, feline herpes virus type 1 and feline panleucopenia virus

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable *[Comment: will not be mentioned on the packaging item]*

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 30 min.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet before use

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – to be supplied only on veterinary prescription

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4533

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Tricat Trio
for cats (comment: 'for cats' will be expressed in written words and by means of a pictogram)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

≥ 4.6 $\log_{10}$ PFU live att. FCV
≥ 5.2 $\log_{10}$ PFU live att. FVR
≥ 4.3 $\log_{10}$ $CCID_{50}$ live att. FPLV

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

s.c.

5. WITHDRAWAL PERIOD

Not applicable. *[Comment: will not be mentioned on the packaging item]*

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 30 min.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

MSD Animal Health logo

LABELLING DILUENT

Nobivac Solvent
– sterile buffered solution

species expressed in written words and by means of a pictogram

1 dose

EXP

Lot

MSD Animal Health logo

PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer for batch release:
Intervet International B.V.
Wim de Körverstraat 35
NL- 5831 AN Boxmeer

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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%

Lyophilisate and solvent for suspension for injection
Off white lyophilisate

4. INDICATIONS

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 herpes virus type 1 (FHV, feline rhinotracheitis virus) 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 FHV components and 3 weeks for the FPLV component.
The duration of immunity is 1 year for the FCV and FHV components and 3 years for the FPLV component.

5. CONTRAINDICATIONS

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.

6. ADVERSE REACTIONS

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).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

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.
Reconstituted vaccine should be used within 30 minutes.

10. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Lyophilisate: Store in a refrigerator (2-8°C).
Protect from light.
Solvent: can be kept below 25°C if stored separately from the lyophilisate.
Do not freeze.

Do not use after the expiry date stated on the label.

11. SPECIAL WARNING(S)

Only healthy animals should be vaccinated.

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.

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.

In case of accidental self injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

Do not mix with any other veterinary medicinal product.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

13. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

14. OTHER INFORMATION

Pack sizes: 5x, 10x, 25x, 50x 1 dose of vaccine and solvent
Not all pack sizes may be marketed

Approved 14 August 2020