ANNEX III
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 Ducat lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose at least:
$10^{4.8}$ $TCID_{50}$ of feline rhinotracheitis virus, strain G2620A
$10^{4.6}$ PFU of feline calicivirus, strain F9

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cats.

5. INDICATION(S)

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

Keep the vials in the outer box.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5071

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL LABEL - lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Ducat lyophilisate for suspension for injection

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Feline calicivirus ≥ $10^{4.6}$ PFU and feline rhinotracheitis virus ≥ $10^{4.8}$ $TCID_{50}$ per dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 30 min.

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

1 dose

6. ROUTE(S) OF ADMINISTRATION

SC

7. WITHDRAWAL PERIOD

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE SOLVENT LABEL

GLASS VIAL - Solvent

1. NAME OF THE DILUENT/SOLVENT

Nobivac Solvent
– sterile buffered solution

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

3. ROUTES OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

Store below 25 °C.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp. {mm/yyyy}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health logo

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Ducat, lyophilisate and solvent for suspension for injection, for cats

2. COMPOSITION

Each dose (1 ml) of reconstituted vaccine contains:
Active substances:
Live attenuated feline rhinotracheitis virus, strain G2620A: $\geq 10^{4.8}$ $TCID_{50}$[1],
Live attenuated feline calicivirus, strain F9: $\geq 10^{4.6}$ PFU[2].
[1]$TCID_{50}$: Tissue Culture Infectious Dose 50%
[2]PFU: Plaque Forming Units

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

3. TARGET SPECIES

Cats.

4. INDICATIONS FOR USE

Active immunisation of cats to reduce the clinical signs caused by infection with feline rhinotracheitis virus and feline calicivirus infections.

Onset of immunity: 4 weeks.
Duration of immunity: 1 year.

5. CONTRAINDICATIONS

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

6. SPECIAL WARNING(S)

For animal treatment only.

Special warnings:
Vaccination at six weeks of age has been proven to be safe.
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Care should be taken that aerosol is not formed when vaccinating the cat as nasal or oral exposure could result in clinical respiratory signs including lethargy and malaise. For the same reason, the cat should be prevented from licking the injection site.

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.

Pregnancy and lactation:
Do not use during pregnancy or lactation, as the product has not been tested in pregnant or lactating queens.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy from the concurrent use of this vaccine with any other, except the vaccine in the Nobivac range containing rabies antigen, strain Pasteur RIV, where this product and the combined use is authorised. 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.

Overdose:
In the case of an overdose, a transient swelling (≤ 5 mm) at the injection site may occur for four to ten days. A transient increase in temperature (< 40.8 °C) may occur while occasionally lethargy for one day after vaccination may be observed.

Major incompatibilities:
Do not mix with any other vaccine or immunological product except the solvent supplied with the product or with the vaccine in the Nobivac range containing rabies antigen, strain Pasteur RIV (where this product and the combined use is authorised).

7. ADVERSE EVENTS

Cats:

Very common (> 1 animal / 10 animals treated):	Injection site swelling.[1]
Common (1 to 10 animals / 100 animals treated):	Elevated temperature.[2]
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reactions (e.g. pruritus, dyspnoea, vomiting, diarrhoea and collapse including anaphylaxis).[3] Lethargy.[4]
Very rare (< 1 animal /10,000 animals treated, including isolated reports):	Injection site pain.[1] Febrile limping syndrome reactions in kittens.[5]

[1] A local swelling (≤ 5 mm), sometimes painful, may be observed at the injection site for one day post-vaccination.

[2] Elevated body temperature (up to 40 °C) may occur for 1 – 2 days post vaccination.
[3] Sometimes fatal. If such a reaction occurs, appropriate treatment should be administered without delay.
[4] Lethargy may be observed during the first day after vaccination.
[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, ROUTE(S) AND METHOD OF ADMINISTRATION

One ml of the reconstituted vaccine should be given by subcutaneous injection.

Primary vaccination:
Cats from 8 weeks of age onwards should receive two vaccinations with an interval of 3 – 4 weeks.
Revaccination:
Annual booster.

During the initial vaccination course, the vaccine in the Nobivac range containing rabies antigen, strain Pasteur RIV, may be used to reconstitute this vaccine at the vaccination at 12 weeks of age (where this product and the combined use is authorised).

9. ADVICE ON CORRECT ADMINISTRATION

Allow the sterile solvent provided to reach room temperature.
Aseptically reconstitute the lyophilised vaccine with one ml of the solvent. Shake well after addition of the solvent.
Visual appearance of the reconstituted product: off-pink or pink coloured suspension.

10. WITHDRAWAL PERIOD(S)

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 01708/5071

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

March 2023

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

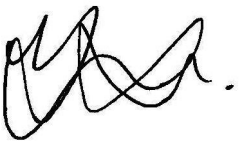
16. CONTACT DETAILS

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:
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

17. OTHER INFORMATION



Approved: 23 March 2023