ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Ducat

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

per dose:
Live att. feline viral rhinotracheitis virus ≥ 4.8 $\log_{10}$ $TCID_{50}$,
Live att. feline calicivirus ≥ 4.6 $\log_{10}$ PFU

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 rhinotracheitis virus and feline calici virus.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous 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. *[Comment: mentioned on the packaging item only once]*

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. *[Comment: mentioned on the packaging item only once]*

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 Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4630

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Ducat live vaccine, for cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

≥ 4.8 $\log_{10}$ $TCID_{50}$ FVR
≥ 4.6 $\log_{10}$ PFU FCV

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.

Intervet logo

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Nobivac Ducat

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 Limited
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 Ducat

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

Per dose of 1 ml reconstituted vaccine:

Live attenuated feline viral rhinotracheitis virus, strain G2620A at least 4.8 $\log_{10}$ $TCID_{50}$*,
Live attenuated feline calicivirus, strain F9 at least 4.6 $\log_{10}$ PFU**.

* tissue culture infectious dose
** plaque forming units

4. INDICATION(S)

Active immunisation of cats against feline viral rhinotracheitis (feline herpes virus type I) and feline calicivirus infections. Vaccination reduces clinical signs caused by these viral infections.
Onset of immunity: 4 weeks
Duration of immunity: 1 year.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

A slight transient, sometimes painful, swelling (≤ 5mm) may be observed at the site of injection for one day. A slight temporary rise in rectal temperature may occur, while occasionally transient lethargy may be observed during the first day after vaccination. In 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

Allow the sterile diluent provided to reach room temperature. Aseptically reconstitute the lyophilised vaccine with one ml of the diluent. Shake well after addition of the diluent. One ml of the reconstituted vaccine should be given by subcutaneous injection.

- Basic vaccination: cats from 8 weeks of age onwards should receive two vaccinations with an interval of 3-4 weeks.
- Revaccination: annual booster

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

9. ADVICE ON CORRECT ADMINISTRATION

The contents of the vial should be used within 30 minutes after reconstitution of the product.

10. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Vaccine: Store in a refrigerator (2 °C – 8 °C). Do not freeze. Protect from light.
Solvent: Store below 25°C if stored independently from the vaccine.

11. SPECIAL WARNING(S)

Vaccination at six weeks of age has been proven to be safe.

Vaccinate only healthy animals. 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.

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other, except Intervets' vaccine containing rabies antigen, strain Pasteur RIV, where this product and the combined use is authorised. A decision to use Nobivac Ducat before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

In the case of an overdose, a transient swelling (≤ 5mm) 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.

Do not mix with any other vaccine or immunological product except the diluent supplied with the product or with Intervets' vaccine containing rabies antigen, strain Pasteur RIV (where this product and the combined use is authorised).

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

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

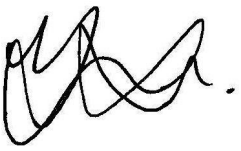
Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

13. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2020

14. OTHER INFORMATION

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



Approved: 10 June 2020