PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

cardboard or plastic box with 10 or 50 x 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac FeLV, suspension for injection for cats
Inactivated vaccine to stimulate active immunity to feline leucosis

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 1 ml:
The vaccine contains per ml 102 µg purified p45 FeLV-envelope antigen, obtained by genetic recombination of the *E. coli* strain.
Adjuvants: / The antigenic suspension is adjuvanted with 1 mg of a 3% aluminium hydroxide gel and with 10µg purified extract of *Quillaja saponaria*.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

Cardboard or plastic box with 10 vials.
Cardboard or plastic box with 50 vials

10 x 1 dose
50 x 1 dose

5. TARGET SPECIES

Pictogram

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: / Dose: 1 ml by subcutaneous administration.

Shake the vial gently before use.
Read package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP : mm/yyyy
EXP end of:

11. SPECIAL STORAGE CONDITIONS

Keep container in the outer packaging.
Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.
Use immediately after first opening.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]
For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4059

17. MANUFACTURER'S BATCH NUMBER

LOT : XXX
Batch: / BN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
vial label 1ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac FeLV, for cats 1 dose (1 ml)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

102 µg purified recombinant p45 FeLV-envelope antigen.

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

1ml

4. ROUTE(S) OF ADMINISTRATION

Route: SC.
Use immediately after first opening.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

LOT : XXX
Batch:

7. EXPIRY DATE

EXP : MM/YYYY
Expiry end of:
EXP end of:

Vm 05653/4059 POM-V

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY.

PACKAGE LEAFLET FOR:

Nobivac FeLV, 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 and manufacturer for batch release
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac FeLV, suspension for injection for cats

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

Content per dose of 1 ml:

Active substance
Minimum quantity of purified p45 FeLV-envelope antigen 102 µg

Adjuvants
3 % aluminium hydroxide gel expressed as mg Al^{3+} 1 mg

Purified extract of *Quillaja saponaria* 10 µg

Excipient
Buffered isotonic solution to 1 ml

Opalescent liquid.

4. INDICATION(S)

For active immunisation of healthy cats to prevent persistent feline leukaemia-virus viraemia and any associated clinical signs of the feline leucosis.

The onset of protection begins 2 weeks after immunisation and the duration of protection lasts one year after the primo-vaccination.

Following a first booster vaccination one year after the primary vaccination course, a duration of immunity of 3 years has been demonstrated.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

Transient and small thickening or nodule, approximately 5 - 10 mm in size, may be observed at the injection site and disappear within 2 to 6 weeks without treatment. Occasionally, systemic reactions (hyperthermia, anorexia, lethargy) may occur within one or two days after vaccine administration. Digestive disturbances (such as emesis and diarrhoea) may also be commonly observed.
Where Nobivac FeLV has been used to reconstitute cat vaccines in the Nobivac range containing feline calicivirus (F9 strain), feline rhinotracheitis virus (G2620A strain) and/or feline panleucopenia virus (MW-1 or Bristol strain) prior to inoculation, a small nodule at the site of vaccination is frequently observed. It can persist for up to 18 days post-inoculation. Occasionally, the nodule may be painful for up to 6 days after injection. A transient rise in body temperature or lameness may occur and last up to 3 days post vaccination. In some cases, a slight dullness or reduced appetite may be observed for up to 1 day post vaccination.
In the rare event of hypersensitivity reaction following vaccination, administer an antihistamine, corticosteroid or adrenaline without delay and by the most-immediate route.
No undesirable effects have been seen after the administration of an overdose of Nobivac FeLV except those indicated above.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

Administer via the subcutaneous route 1 dose (1 ml) of Nobivac FeLV according to the following regimen of vaccination.

Basic vaccination scheme
A first injection in cats from minimum 8 weeks of age.
A second injection of cats 3 to 4 weeks later.

Re-vaccination scheme
Following a first booster vaccination one year after the primary vaccination course, subsequent vaccinations can be performed at intervals of three years.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial gently before use.
Nobivac FeLV can be used to reconstitute 1 dose (1 vial) of cat vaccines of the Nobivac range containing feline calicivirus (F9 strain), feline rhinotracheitis virus (G2620A strain) and/or feline panleucopenia virus (MW-1 or Bristol strain) immediately prior to use by the addition of the contents of one vial (1 ml) of Nobivac FeLV.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.
Keep out of the sight and reach of children.
Do not use after the expiry date stated on the label and outer packaging.
Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL WARNING(S)

Special precautions for use in animals
The vaccine should be administered in accordance with the usual aseptic conditions for vaccination.
Vaccinate only healthy animals.
It is recommended that animals be treated for intestinal parasites at least 10 days prior to vaccination.
Operator warnings
In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Interactions
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with cat vaccines of the Nobivac range containing feline

calicivirus (F9 strain), feline rhinotracheitis virus (G2620A strain) and/or feline panleucopenia virus (MW-1 or Bristol strain).
Do not mix with other medicinal products except cat vaccines of the Nobivac range containing feline calicivirus (F9 strain), feline rhinotracheitis virus (G2620A strain) and/or feline panleucopenia virus (MW-1 or Bristol strain).
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. A decision to use this vaccine before or after another veterinary medicinal product therefore needs to be made on a case by case basis.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused product or waste material should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2023

15. OTHER INFORMATION

For animal treatment only.
ATCVet code: QI06AA01. Inactivated viral vaccine. Vaccine against feline leukaemia. The vaccine contains the purified p45 FeLV-envelope antigen, obtained by genetic recombination of the *E. coli* strain. The antigen suspension is adjuvanted with an aluminium hydroxide gel and with a purified extract of *Quillaja saponaria*.
Pack sizes
Cardboard or plastic boxes containing 10 or 50 one dose vials of vaccine
Not all pack sizes may be marketed.

Protection against persistent viraemia is observed in 73% of cats 3 weeks after their first vaccine injection.

MA number
Vm 05653/4059

Distributor in the UK
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

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To be supplied only on veterinary prescription

Approved 29 August 2023