ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic or cardboard box containing 2 or 5 vials of lyophilisate and 2 or 5 vials or solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MUSTELIGEN D lyophilisate and solvent for suspension for injection for ferrets

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1ml contains:

Active substance
Lyophilisate
Live attenuated distemper virus, Lederle strain $10^{2.9} - 10^{5.1}$ $CCID_{50}$*
* Cell culture infectious dose 50%

Solvent
Water for injections 1 ml

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

2 vials of lyophilisate and 2 vials of solvent
5 vials of lyophilisate and 5 vials of solvent

5. TARGET SPECIES

Ferrets.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

Disposal: read package leaflet.

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 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 – 2065 m - LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4227

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MUSTELIGEN D lyophilisate for ferrets

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

D

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

Not applicable

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

Ad us. vet./For animal treatment only

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MUSTELIGEN D solvent

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Aqua pro inj./WFI

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

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Ad us. vet./For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
MUSTELIGEN D lyophilisate and solvent for suspension for injection for ferrets

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 responsible for batch release:
Virbac
1ère avenue – 2065 m - LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MUSTELIGEN D lyophilisate and solvent for suspension for injection for ferrets

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

Each dose of 1ml contains:

Active substance
Lyophilisate
Live attenuated distemper virus, Lederle strain $10^{2.9} - 10^{5.1}$ $CCID_{50}$*
* Cell culture infectious dose 50%

Solvent
Water for injections 1 ml

Lyophilisate: White pellet.
Solvent: Colourless liquid.

4. INDICATION(S)

For active immunisation of ferrets from 9 weeks of age to prevent mortality and clinical signs caused by distemper virus.
Onset of immunity: 3 weeks
Duration of immunity: 1 year.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Transient slight apathy, hyperthermia or digestive disturbances (such as diarrhoea, decreased appetite, anorexia, vomiting) which resolve spontaneously were very commonly observed in safety studies.
A moderate swelling (≤1.5 cm) at the injection site sometimes associated with pain and which resolves spontaneously within one day was commonly observed in safety studies. Erythema at the injection site was uncommonly observed in safety studies.
Hypersensitivity reactions may be observed in some animals in very rare cases. In case of such an allergic or anaphylactic reaction, appropriate symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Ferrets.

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

Subcutaneous use. One dose of 1 ml.

Vaccination schedule:
Primary vaccination course:
- first injection from 9 weeks of age
- second injection 4 weeks later.

Re-vaccination: annual

9. ADVICE ON CORRECT ADMINISTRATION

After reconstitution of the lyophilisate with the solvent, shake gently and administer immediately according to vaccination schedule.

The appearance of the reconstituted product is slightly pinkish-beige.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

Special warning for each target species:
Vaccinate healthy animals only

Special precautions for use in animals:
Vaccination is recommended for ferrets over 350g for males and over 300g for females because a lower tolerance has been observed in animals of lighter weights.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. The use is not recommended during pregnancy or lactation.

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.

Overdose (symptoms, emergency procedures, antidotes):
Administration of 10 doses of the vaccine in one single injection site showed no systemic reactions and no other local reactions than those mentioned in the section “Adverse reactions”, except for a nodule (< 1 cm) or a slight local oedema due to the large volume administered that was very commonly observed in the 10-fold overdose study.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.

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

Medicines should not be disposed of via wastewater or household waste
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Immediate packaging:
Lyophilisate: Type 1 glass vial with an elastomer stopper coated with a fluorocarbon polymer resin and an aluminium cap.
Solvent : Type 1 glass vial with an elastomer stopper and an aluminium cap.

Pack sizes:
Plastic or cardboard box containing 2 vials of lyophilisate (1 dose) and 2 vials of solvent (1 ml)
Plastic or cardboard box containing 5 vials of lyophilisate (1 dose) and 5 vials of solvent (1 ml)

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 01 June 2020