SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MUSTELIGEN D lyophilisate and solvent for suspension for injection for ferrets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: White pellet.
Solvent: Colourless liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Ferrets.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

After reconstitution of the lyophilisate with the solvent, shake gently and administer immediately one dose of 1 ml subcutaneously according to the following vaccination schedule:

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

Re-vaccination: annual

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for ferret - live viral vaccines - ferret distemper virus. ATCvet code: QI20DD01

The product stimulates active immunity against distemper virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Gelatine
Potassium hydroxide
Lactose monohydrate
Glutamic acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Water for injections
Sodium chloride
Disodium phosphate

Solvent
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Virbac
1ère avenue - 2065 m - LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4227

9. DATE OF FIRST AUTHORISATION

01 June 2020

10. DATE OF REVISION OF THE TEXT

June 2020

Approved 01 June 2020