

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC DUOPARVO emulsion and suspension for emulsion for injection for Muscovy ducks

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.2 ml dose of vaccine contains:

Active substances:

Live attenuated Derzsy's Disease virus, Hoekstra strain: between $10^{3.7}$ and $10^{5.0}$ TCID₅₀*

Inactivated Muscovy Duck ParvoVirus, OLM2017 strain: $\geq 10^{7.2}$ genomic copies

*TCID₅₀: 50% tissue culture infectious dose

Adjuvant:

Light paraffin oil.....0.08 ml

Excipients

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
<u>Muscovy duck parvovirus emulsion</u> Macrogol cetostearyl ether Macrogol stearate Sorbitan Trioleate Polysorbate Sodium disulfite Thiomersal Water for injection	0.03 mg
<u>Derzsy's disease virus suspension</u> Newborn calf serum	

3. CLINICAL INFORMATION

3.1 Target species

Muscovy ducks.

3.2 Indications for use for each target species

For the active immunisation of Muscovy ducks from 1 day of age onwards to reduce mortality and clinical signs of Muscovy duck parvovirus and Derzsy's disease.

To reduce the excretion of parvovirus from the ducklings.

Onset of immunity: 4 days after vaccination.

Duration of immunity: 5 weeks.

The duration of immunity protects the birds during the period when they are most susceptible to Muscovy duck parvovirus and Derzsy's disease

3.3 Contraindications

None

3.4 Special warnings

Vaccinate healthy animals only.

CEVAC DUOPARVO is composed of an emulsion vial and a suspension vial. Efficacy against parvovirus has been demonstrated only after vaccination with the reconstituted vaccine consisting of the suspension mixed in the emulsion vial.

The available data do not allow to exclude the influence of maternally derived antibodies on the efficacy of the vaccination.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The live vaccine strain Hoekstra has shown shedding and spreading for at least 3 weeks. Unvaccinated animals should not be mixed with animals vaccinated with CEVAC DUOPARVO.

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.

To the user:

This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

Other precautions: None

3.6 Adverse events

Muscovy ducks: None

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds :

Do not use in birds in lay.

3.8 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.

3.9 Administration routes and dosage

For subcutaneous use.

Administer one dose of 0.2 ml of reconstituted product by subcutaneous injection (lower part of the neck) at one day of age.

Shake the vials, then transfer the content of the “Derzsy’s Disease virus suspension L” vial into the “Muscovy duck parvovirus emulsion K” vial with a sterile syringe and needle. Gently shake the emulsion K vial to mix the antigens. After mixing, the product is ready for use.

Vaccine temperature should be around 15-25°C before being used.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The administration of an overdose of CEVAC DUOPARVO may be associated with transient mild skin redness at the injection site, and with a transient decrease in the duckling growth rates compared to unvaccinated non-exposed ducklings.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

Pharmacotherapeutic group: live goose parvovirus + inactivated duck parvovirus

ATCvet code: QI01BH01

The vaccine induces an active and specific immunisation of ducks against Muscovy duck parvovirus and Derzsy’s disease in the vaccinated animals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the suspension as packaged for sale: 18 months

Shelf life of the emulsion as packaged for sale: 18 months

Shelf life after dilution according to directions: 4 hours

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

5.4 Nature and composition of immediate packaging

500 doses:

Type I glass bottles closed with nitrile rubber stoppers and aluminium caps:

1 suspension vial with 15 ml vaccine and 1 emulsion vial with 85 ml vaccine

5 suspension vials with 15 ml vaccine and 5 emulsion vials with 85 ml vaccine

1500 doses:

Type I glass bottles closed with nitrile rubber stoppers and aluminium caps and polypropylene bottles closed with nitrile rubber stoppers and aluminium caps:

1 suspension type 1 glass vial with 45 ml vaccine and 1 emulsion polypropylene vial with 255 ml vaccine

5 suspension type 1 glass vials with 45 ml vaccine and 5 emulsion polypropylene vials with 255 ml vaccine

Secondary packaging: cardboard box.

Not all pack sizes may be marketed.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

FILAVIE
20, LA CORBIERE ROUSSAY
49450 SEVREMOINE
FRANCE

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**CARDBOARD BOX****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

CEVAC DUOPARVO emulsion and suspension for emulsion for injection for Muscovy ducks

2. STATEMENT OF ACTIVE SUBSTANCES

Live attenuated Derzsy's Disease virus, Hoekstra strain: between $10^{3.7}$ and $10^{5.0}$ TCID₅₀*

Inactivated Muscovy Duck ParvoVirus, OLM2017 strain: $\geq 10^{7.2}$ genomic copies

*TCID₅₀: 50% tissue culture infectious dose

3. PACKAGE SIZE

500 doses

1500 doses

4. TARGET SPECIES

Muscovy ducks.

5. INDICATIONS

Read the package leaflet.

6. ROUTES OF ADMINISTRATION

Subcutaneous injection

7. WITHDRAWAL PERIODS

Withdrawal period: zero days

8. EXPIRY DATE

Exp {mm/yyyy}

Once reconstituted, use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

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”
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Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

FILAVIE
20, LA CORBIERE ROUSSAY
49450 SEVREMOINE
FRANCE

14. MARKETING AUTHORISATION NUMBERS
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15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

TYPE I GLASS BOTTLE (500 DOSES) OR POLYPROPYLENE BOTTLES (1500 DOSES)
DERZSKY'S DISEASE VIRUS SUSPENSION L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DERZSKY'S DISEASE VIRUS SUSPENSION L

2. STATEMENT OF ACTIVE SUBSTANCES

Live attenuated Derzsy's Disease virus, Hoekstra strain: between $10^{3.7}$ and $10^{5.0}$ TCID₅₀*
*TCID₅₀: 50% tissue culture infectious dose

3. TARGET SPECIES

Muscovy ducks

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days

6. EXPIRY DATE

Exp {mm/yyyy}

Once reconstituted, use within 4 hours

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

FILAVIE
20, LA CORBIERE ROUSSAY
49450 SEVREMOINE
FRANCE

9. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

TYPE I GLASS BOTTLE (500 DOSES) OR POLYPROPYLENE BOTTLES (1500 DOSES)
MUSCOVY DUCK PARVOVIRUS EMULSION K

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MUSCOVY DUCK PARVOVIRUS EMULSION K

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated Muscovy Duck ParvoVirus OLM2017 strain: $\geq 10^{7.2}$ genomic copies

3. TARGET SPECIES

Muscovy ducks

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days

6. EXPIRY DATE

Exp {mm/yyyy}

Once reconstituted, use within 4 hours

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Protect from light.

Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

FILAVIE
20, LA CORBIERE ROUSSAY
49450 SEVREMOINE
FRANCE

9. BATCH NUMBER

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
TYPE I GLASS BOTTLE (500 DOSES) OR POLYPROPYLENE BOTTLES (1500 DOSES)
DUOPARVO DERZSKY'S DISEASE VIRUS SUSPENSION L (15ml)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DERZSKY'S DISEASE VIRUS SUSPENSION L for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Live attenuated Derzsy's Disease, Hoekstra strain: : between $10^{3.7}$ and $10^{5.0}$ TCID₅₀*

*TCID₅₀: 50% tissue culture infectious dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

CEVAC DUOPARVO emulsion and suspension for emulsion for injection for Muscovy ducks

2. Composition

Each 0.2 ml dose of vaccine contains:

Live attenuated Derzsy's Disease virus, Hoekstra strain: between $10^{3.7}$ and $10^{5.0}$ TCID₅₀*

Inactivated Muscovy Duck ParvoVirus, OLM2017 strain: $\geq 10^{7.2}$ genomic copies / mL

*TCID₅₀: 50% tissue culture infectious dose

Adjuvant : Light paraffin oil.....0.08ml

3. Target species

Muscovy duck

4. Indications for use

For the active immunisation of Muscovy ducks from 1 day of age onwards to reduce mortality and clinical signs of Muscovy duck parvovirus and Derzsy's disease.

To reduce the excretion of parvovirus from the duckling.

Onset of immunity: 4 days after vaccination.

Duration of immunity: 5weeks.

The duration of immunity protects the birds during the period when they are most susceptible to Muscovy duck parvovirus and Derzsy's disease.

5. Contraindications

None.

6. Special warnings

Special warnings: Vaccinate only healthy animals.

CEVAC DUOPARVO is composed of an emulsion vial and a suspension vial. Efficacy against parvovirus has been demonstrated only after vaccination with the reconstituted vaccine consisting of the suspension mixed in the emulsion vial.

The available data do not allow to exclude the influence of maternally derived antibodies on the efficacy of the vaccination.

The live vaccine strain Hoekstra has shown shedding and spreading for at least 3 weeks. Unvaccinated animals should not be mixed with animals vaccinated with CEVAC DUOPARVO.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user: The accidental injection or self-injection of this oil base product may cause strong pain or swelling, in particular if injected into a joint or finger. In these later cases it is essential that the

medical care is given by a specialist. People with known hypersensitivity to any of the excipient should administer the product with caution.

To the physician: This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even in a loss of a digit. Expert and prompt surgical attention is required and may necessitate early incision and irrigation of the injected area, especially when there is involvement of finger pulp or tendon.

Laying birds:

Do not use in birds in lay.

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:

The administration of an overdose of CEVAC DUOPARVO may be associated with transient mild skin redness at the injection site, and with a transient decrease in the duckling growth rates compared to unvaccinated non-exposed ducklings.

Major incompatibilities: Do not mix with any other veterinary medicinal product.

7. Adverse events

Muscovy ducks: none

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 marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Ducklings:

Administer one dose of 0.2 ml by subcutaneous injection (lower part of the neck) from 1 day of age.

9. Advice on correct administration

Shake the vials, then transfer the content of the “Derzsy’s Disease virus suspension L” vial into the “Muscovy duck parvovirus emulsion K” vial with a sterile syringe and needle. Gently shake the emulsion K vial to mix the antigens. After mixing, the product is ready for use.

Vaccine temperature should be around 15-25°C before being used.

10. Withdrawal periods

Zero days

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (+2°C / +8°C).

Protect from light.

Do not freeze.

Shelf life of the suspension as packaged for sale: 18 months

Shelf life of the emulsion as packaged for sale: 18 months

Shelf life after dilution according to directions: 4 hours

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

500 doses and 1500 doses.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions

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