**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvoduk concentrate and solvent for suspension for injection for Muscovy ducks

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each reconstituted dose of 0.2 ml contains:

**Active substance:**

Live attenuated Muscovy duck parvovirus strain GM 199 ..... 2.6–4.8 $\log_{10}$ $CCID_{50}$*
* Cell culture infectious dose 50%.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Concentrate and solvent for suspension for injection.

The concentrate is opalescent and homogeneous.
The solvent is clear and colourless.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Muscovy ducks.

### 4.2 Indications for use, specifying the target species

Active immunisation of Muscovy ducks to reduce weight loss and lesions of Muscovy duck parvovirosis and Derzsy's disease and, in the absence of maternally derived antibodies, to also prevent mortality.

Onset of immunity: 11 days after the primary vaccination course

Duration of immunity: 26 days after the primary vaccination course

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

### 4.3 Contraindications

Do not use in birds in lay.

### 4.4 Special warnings for each target species

Vaccinate healthy animals only.

## 4.5 Special precautions for use

Special precautions for use in animals

The entire flock should be vaccinated to lower the risk of any circulation of the vaccine strain and virus recombination.

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

Not applicable.

## 4.6 Adverse reactions (frequency and seriousness)

None.

## 4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay (see section 4.3).

## 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

Subcutaneous use.

Administer one dose of 0.2 ml by subcutaneous injection according to the following vaccination scheme:

- First vaccination: at 1 day of age.
- Second vaccination: at 17 days of age.

Shake the vial of antigen concentrate. Insert the trocar provided with the bag of solvent through the closures of both the glass vial and the solvent bag to connect them. Transfer the content of the glass vial into the bag of solvent. Then remove the trocar from both containers. Gently shake the bag to mix the antigen concentrate with the solvent. After mixing, connect the bag to a high-speed, automated or semi-automated injection system. The vaccine is then ready to use.

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

No adverse reactions were observed after the administration of an overdose (10 x the dose).

## 4.11 Withdrawal period(s)

Zero days.

# 5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live viral vaccines, duck parvovirus.
ATCvet code: QI01BD03.

The vaccine contains a live attenuated Muscovy duck parvovirus. It induces an active and specific immunity against Muscovy duck parvovirosis and Derzsy's disease in the vaccinated birds.

Eleven genetic markers (nucleotides) in the VP1 gene allow differentiation of the Parvoduk vaccine strain from the field strains of duck and goose parvovirus, as shown below:

| Position on VP1 gene | 8 | 19 | 132 | 649 | 957 | 1769 | 1790 | 1858 | 1933 | 2100 | 2198 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Parvoduk | A | G | T | C | T | A | T | C | G | A | G |
| Duck Parvovirus | C | A | C | G | C | C | C | A | A | C | A |
| Goose Parvovirus | C | T | C | G | C | C | C | A | A | T | A |

The vaccine strain can be found in the spleen for at least 35 days.

In ducklings free of maternally derived antibodies a single vaccination at day 1 will lead to an onset of immunity after 14 days.

A small occasional impact on growth cannot be excluded upon vaccination of day-old ducklings free of maternally derived antibodies.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Concentrate:
Casein hydrolysate
Aluminium hydroxide

Solvent:
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate dehydrate
Water for injections.

### 6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale : 2 years
Shelf life after dilution according to directions: 4 hours.

### 6.4 Special precautions for storage

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

Solvent:
Store below 25 °C.
Do not freeze.

Protect from light.

### 6.5 Nature and composition of immediate packaging

Antigen concentrate:
Type I glass vials with butyl elastomer closure.
Cardboard box of 10 vials of 500 doses.
Cardboard box of 1 vial of 2,500 doses.

Solvent:
Polypropylene bags with butyl elastomer closure and trocar.
Cardboard box of 10 bags of 500 doses.
Cardboard box of 1 bag of 2,500 doses.

### 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

MERIAL
29, avenue Tony Garnier
69007 Lyon
FRANCE

## 8. MARKETING AUTHORISATION NUMBERS

EU/2/14/162/001–002

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11/04/2014
Date of last renewal:

## 10. DATE OF REVISION OF THE TEXT

Detailed information of this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

## PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

# ANNEX II

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE**

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

**C. STATEMENT OF THE MRLs**

## A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) of the biological active substance(s)

MERIAL
Laboratoire Lyon Gerland
254, rue Marcel Mérieux
69007 Lyon
FRANCE

Name and address of the manufacturer(s) responsible for batch release

MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
FRANCE

## B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question

## C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

**A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box of concentrate**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvoduk concentrate for suspension for injection for Muscovy ducks

## 2. STATEMENT OF ACTIVE SUBSTANCES

One reconstituted dose of 0.2 ml contains:
Live attenuated Muscovy duck parvovirus strain GM 199 ..... 2.6–4.8 $\log_{10}$ $CCID_{50}$.

## 3. PHARMACEUTICAL FORM

Concentrate for suspension for injection.

## 4. PACKAGE SIZE

10 x 500 doses
1x 2,500 doses

## 5. TARGET SPECIES

Muscovy ducks.

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous use.

## 8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP
Once diluted use within 4 hours.

## 11. SPECIAL STORAGE CONDITIONS

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

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

Read the package leaflet before use.

## 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

MERIAL
29, avenue Tony Garnier
69007 Lyon
FRANCE

## 16. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/162/001
EU/2/14/162/002

## 17. MANUFACTURER'S BATCH NUMBER

Lot

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box of solvent**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvoduk solvent for suspension for injection for Muscovy ducks

## 2. STATEMENT OF ACTIVE SUBSTANCES

Saline buffer

## 3. PHARMACEUTICAL FORM

## 4. PACKAGE SIZE

10 x 500 doses
1x 2,500 doses

## 5. TARGET SPECIES

Muscovy ducks.

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP

## 11. SPECIAL STORAGE CONDITIONS

Store below 25° C.
Do not freeze.
Protect from light.

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

Read the package leaflet before use.

## 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

MERIAL
29, avenue Tony Garnier
69007 Lyon
FRANCE

## 16. MARKETING AUTHORISATION NUMBERS

EU/2/14/162/001
EU/2/14/162/002

## 17. MANUFACTURER'S BATCH NUMBER

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Vials of concentrate**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvoduk concentrate for suspension for injection for Muscovy ducks

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live attenuated Muscovy duck parvovirus.

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

500 doses
2,500 doses

## 4. ROUTE(S) OF ADMINISTRATION

SC

## 5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

## 6. BATCH NUMBER

Lot

## 7. EXPIRY DATE

EXP
Once diluted, use within 4 hours.

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Bags of solvent**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Parvoduk concentrate

## 2. STATEMENT OF ACTIVE SUBSTANCES

Saline buffer

## 3. PHARMACEUTICAL FORM

## 4. PACKAGE SIZE

500 doses.
2,500 doses.

## 5. TARGET SPECIES

Muscovy ducks.

## 6. INDICATION(S)

Read the package leaflet before use.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP

## 11. SPECIAL STORAGE CONDITIONS

Store below 25° C.
Do not freeze.
Protect from light.

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

Read the package leaflet before use.

## 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 the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MERIAL
29, avenue Tony Garnier
69007 Lyon
FRANCE

## 16. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/162/001
EU/2/14/162/002

## 17. MANUFACTURER'S BATCH NUMBER

Lot

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**
**Parvoduk concentrate and solvent for suspension for injection for Muscovy ducks**

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MERIAL
29 avenue Tony Garnier
69007 Lyon,
FRANCE

Manufacturer responsible for batch release:
MERIAL
Laboratory of Lyon Porte des Alpes
Rue de l'Aviation,
69800 Saint Priest
FRANCE

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvoduk concentrate and solvent for suspension for injection for Muscovy ducks

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

Each reconstituted dose of 0.2 ml contains:

Active substance:

Live attenuated Muscovy duck parvovirus strain GM 199 ..... 2.6–4.8 $\log_{10}$ $CCID_{50}$*
* Cell culture infectious dose 50%.

Concentrate and solvent for suspension for injection.

The concentrate is opalescent and homogeneous.
The solvent is clear and colourless.

## 4. INDICATION(S)

Active immunisation of Muscovy ducks to reduce weight loss and lesions of Muscovy duck parvovirosis and Derzsy's disease and, in the absence of maternally derived antibodies, to also prevent mortality.

Onset of immunity: 11 days after the primary vaccination course

Duration of immunity: 26 days after the primary vaccination course

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

## 5. CONTRAINDICATIONS

Do not use in birds in lay.

## 6. ADVERSE REACTIONS

None.

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.

## 7. TARGET SPECIES

Muscovy ducks.

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

For subcutaneous use.

Administer one dose of 0.2 ml by subcutaneous injection according to the following vaccination scheme:

- First vaccination: at 1 day of age.
- Second vaccination: at 17 days of age.

## 9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial of antigen concentrate. Insert the trocar provided with the bag of diluent through the closures of both the glass vial and the diluent bag to connect them. Transfer the content of the glass vial into the bag of diluent. Then remove the trocar from both containers. Gently shake the bag to mix the antigen concentrate with the diluent. After mixing, connect the bag to a high-speed, automated or semi-automated injection system. The vaccine is then ready to use. Once reconstituted, use within 4 hours.

## 10. WITHDRAWAL PERIOD(S)

Zero days.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Solvent:
Store below 25 °C.
Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP.

Shelf life after dilution according to directions: 4 hours

## 12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precaution for use in animals:
The entire flock should be vaccinated to lower the risk of any circulation of the vaccine strain and virus recombination.

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

Lay:
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 medicine. 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):
No adverse reactions were observed after the administration of an overdose (10x the dose).

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

## 15. OTHER INFORMATION

The vaccine contains a live attenuated Muscovy duck parvovirus. It induces an active and specific immunity against Muscovy duck parvovirosis and Derzsy's disease in the vaccinated birds.

Eleven genetic markers (nucleotides) in the VP1 gene allow differentiation of the Parvoduk vaccine strain from the field strains of duck and goose parvovirus, as shown below:

| Position on VP1 gene | 8 | 19 | 132 | 649 | 957 | 1769 | 1790 | 1858 | 1933 | 2100 | 2198 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Parvoduk | A | G | T | C | T | A | T | C | G | A | G |
| Duck Parvovirus | C | A | C | G | C | C | C | A | A | C | A |
| Goose Parvovirus | C | T | C | G | C | C | C | A | A | T | A |

The vaccine strain can be found in the spleen for at least 35 days.

In ducklings free of maternally derived antibodies a single vaccination at day 1 will lead to an onset of immunity after 14 days.

A small occasional impact on growth cannot be excluded upon vaccination on day-old ducklings free of maternally derived antibodies.

Pack sizes:

Concentrate suspension:
Cardboard box of 10 vials of 500 doses.
Cardboard box of 1 vial of 2,500 doses.

Solvent:
Cardboard box of 10 bags of 500 doses.
Cardboard box of 1 bag of 2,500 doses.

Not all pack sizes may be marketed.

**ANNEX IV**

**GROUNDS FOR ONE ADDITIONAL RENEWAL**

Due to the limited period the veterinary medicinal product Parvoduk has been placed on the market and the consequently limited post-marketing safety information, the CVMP at their meeting on 6-8 November 2018 decided that one five-year renewal is required.