ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProteqFlu-Te
Suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose contains:

Active substances:
Influenza A/equi-2/Ohio/03 [H_3N_8] recombinant Canarypox virus (vCP2242) ..... ≥ 5.3 log10 $FAID_{50}$*
Influenza A/equi-2/Newmarket/2/93 [H_3N_8] recombinant Canarypox virus (vCP1533)
..... ≥ 5.3 log10 $FAID_{50}$*
*Fluorescent assay infectious dose 50 %
Clostridium tetani toxoid ..... ≥ 30 IU**
** antitoxic antibody titre induced after repeated vaccination in guinea pig sera according to Ph. Eur.
Adjuvant:
Carbomer ..... 4 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

Active immunisation of horses of 4 months of age or older against equine influenza to reduce clinical signs and virus excretion after infection, and against tetanus to prevent mortality.
Onset of immunity: 14 days after primary vaccination course.
Duration of immunity induced by the vaccination scheme:
- 5 months after the primary vaccination course;
- after the primary vaccination course and the booster injection 5 months later: 1 year with regard to equine influenza and 2 years with regard to tetanus.

4.3 Contraindications

None.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals
Only healthy animals should be vaccinated.

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.

4.6 Adverse reactions (frequency and seriousness)

- A transient swelling (max. diameter 5 cm) which regresses within 4 days may appear at the injection site.
- Pain and local hyperthermia can occur in rare cases.
- A slight increase in temperature (max. 1.5 °C) may occur for 1 day, exceptionally 2 days.
- In exceptional circumstances, apathy and reduced appetite may be observed the day after vaccination.
- In exceptional circumstances a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but at different sites and not mixed with MERIAL's inactivated vaccine against rabies.

4.9 Amounts to be administered and administration route

For intramuscular use.
For the administration of the vaccine, use sterile and antiseptic-free and/or disinfectant-free material.
Shake the vaccine gently before use.

Administer one dose (1 ml), by intramuscular injection, preferably in the neck region, according to the following schedule:
- primary vaccination course with ProteqFlu-Te: first injection from 5–6 months of age, second injection 4-6 weeks later.
- Revaccination:
  - 5 months after primary vaccination course with ProteqFlu-Te.
  - Followed by:
    - against tetanus: injection of 1 dose at an interval of maximum 2 years with ProteqFlu-Te.
    - against equine influenza: injection of 1 dose every year, alternatively with ProteqFlu or ProteqFlu-Te, respecting an interval of maximum 2 years for the tetanus component.

In case of increased infection risk or insufficient colostrum intake, an additional initial injection of ProteqFlu-Te can be given at the age of 4 months followed by the full vaccination programme (primary vaccination course at 5–6 months of age and 4–6 weeks later followed by revaccination).

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

Following the administration of overdoses of vaccine, no side-effects other than those described under section 4.6 have been observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: QI05AI01.

The vaccine stimulates active immunity against equine influenza and tetanus.

The vaccine strains vCP2242 and vCP1533 are recombinant canarypox viruses expressing the haemagglutinin *HA* gene from the equine influenza virus strains A/equi-2/Ohio/03 (American strain) and A/equi-2/Newmarket/2/93 (European strain), respectively. After inoculation, the viruses do not multiply in the horse but express the protective proteins. As a consequence, these components induce immunity against equine influenza virus (H_3N_8).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Sodium chloride
Disodium hydrogen orthophosphate
Monopotassium phosphate anhydrous
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

18 months.
Use immediately after opening.

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

Type I glass vial.
Butyl elastomer closure and aluminium cap.

Box of 10 vials of 1 dose.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

MERIAL
29 Avenue Tony Garnier
F-69007 Lyon
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/03/038/005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6/03/2003 / 11/01/2008

10 DATE OF REVISION OF THE TEXT

Detailed information on 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

Not applicable.

ANNEX II

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

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

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

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

Influenza component:
MERIAL, Laboratoire Porte des Alpes
Rue de l'Aviation, F-69800 Saint Priest, France

Manufacturing Authorisation issued on 14 August 1997 by the National Agency for Veterinary Medicinal Products, France.

MERIAL, Laboratory of Lyon Gerland
254, Avenue Marcel Mérieux, 69007 Lyon, France

Manufacturing Authorisation issued on 14 August 1997 by the National Agency for Veterinary Medicinal Products, France.

Tetanus component:
MERIALToulouse
4, chemin du Calquet, 31057 Toulouse Cedex, France

Manufacturing Authorisation issued on 23/06/2003 by the National Agency for Veterinary Medicinal Products, France.

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

MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
F-69800 Saint Priest
France

Manufacturing Authorisation issued on 14 August 1997 by the National Agency for Veterinary Medicinal Products, France.

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

Not applicable.

D. 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) 470/2009.

The excipients, including adjuvants, listed in section 6.1 of the SPC are either allowed substances for which table 1 if 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 product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer package for 10 doses: 10 vials of 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProteqFlu-Te
Suspension for injection for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose contains:
Active substances:
Influenza A/equi-2/Ohio/03 [H_3N_8] (vCP2242) ..... ≥ 5.3 log10 $FAID_{50}$
Influenza A/equi-2/Newmarket/2/93 [H_3N_8] (vCP1533) ..... ≥ 5.3 log10 $FAID_{50}$

Clostridium tetani toxoid ..... ≥ 30 IU
Adjuvant:
Carbomer ..... 4 mg

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 doses: 10 vials of 1 dose

5. TARGET SPECIES

Horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP
Use immediately after opening.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated 2 °C-8 °C. Do not freeze. Protect from light.

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

See section 7.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MERIAL
29 Avenue Tony Garnier
F-69007 Lyon
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/03/038/005

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProteqFlu-Te

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read the package leaflet before use.

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
ProteqFlu-Te
Suspension for injection for horses

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,
F-69007 Lyon,
France

Manufacturer for the batch release:
MERIAL,
Laboratoire Porte des Alpes,
Rue de l'Aviation,
F-69800 Saint Priest,
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProteqFlu-Te
Suspension for injection for horses

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

One dose contains:

Active substances:
Influenza A/equi-2/Ohio/03 [H_3N_8] recombinant Canarypox virus (vCP2242) ..... ≥ 5.3 log10 $FAID_{50}$*
Influenza A/equi-2/Newmarket/2/93 [H_3N_8] recombinant Canarypox virus (vCP1533)
..... ≥ 5.3 log10 $FAID_{50}$*
*Fluorescent assay infectious dose 50 %
Clostridium tetani toxoid .....≥ 30 -IU**
** antitoxic antibody titre induced after repeated vaccination in guinea pig sera according to Ph. Eur.
Adjuvant:
Carbomer..... 4 mg

4. INDICATION(S)

Active immunisation of horses of 4 months of age or older against equine influenza to reduce clinical signs and virus excretion after infection, and against tetanus to prevent mortality.
Onset of immunity: 14 days after primary vaccination course.
Duration of immunity induced by the vaccination scheme:
- 5 months after the primary vaccination course;
- after the primary vaccination course and the booster injection 5 months later: 1 year with regard to equine influenza and 2 years with regard to tetanus.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

- A transient swelling (max. diameter 5 cm) which regresses within 4 days may appear at the injection site.
- Pain and local hyperthermia can occur in rare cases.
- A slight increase in temperature (max. 1.5 °C) may occur for 1 day, exceptionally 2 days.
- In exceptional circumstances, apathy and reduced appetite may be observed the day after vaccination.
- In exceptional circumstances a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses

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

Administer one dose (1 ml), by intramuscular injection, preferably in the neck region, according to the following schedule:

- primary vaccination course with ProteqFlu-Te: first injection from 5–6 months of age, second injection 4–6 weeks later.
- Revaccination:
  - 5 months after primary vaccination course with ProteqFlu-Te.
  - Followed by:
    - against tetanus: injection of 1 dose at an interval of maximum 2 years with ProteqFlu-Te.
    - against equine influenza: injection of 1 dose every year, alternatively with ProteqFlu or ProteqFlu-Te, respecting an interval of maximum 2 years for the tetanus component.

In case of increased infection risk or insufficient colostrum intake, an additional initial injection of ProteqFlu-Te can be given at the age of 4 months followed by the full vaccination programme (primary vaccination course at 5–6 months of age and 4–6 weeks later followed by revaccination).

9. ADVICE ON CORRECT ADMINISTRATION

For the administration of the vaccine, use sterile and antiseptic-free and/or disinfectant-free material.
Shake the vaccine gently before use.
Intramuscular use (preferably in the neck region).

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

- Keep out of the reach and sight of children.
- Store and transport refrigerated 2 °C-8 °C. Do not freeze. Protect from light.
- Use immediately after opening.

- Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

- Only healthy animals should be vaccinated.
- Do not mix with any veterinary medicinal product.
- In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
- Can be used during pregnancy and lactation.
- No interaction has been observed when the vaccine was administered simultaneously, but at a separate site, with MERIAL's inactivated vaccine against rabies.
- Following the administration of overdoses of vaccine, no side-effects other than those described under "Adverse reactions" have been observed.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. OTHER INFORMATION

The vaccine stimulates active immunity against equine influenza and tetanus.

The vaccine strains vCP2242 and vCP1533 are recombinant canarypox viruses expressing the haemagglutinin *HA* gene from the equine influenza virus strains A/equi-2/Ohio/03 (American strain) and A/equi-2/Newmarket/2/93 (European strain), respectively. After inoculation, the viruses do not multiply in the horse but express the protective proteins. As a consequence, these components induce immunity against equine influenza virus (H_3N_8).

Box of 10 vials of 1 dose.

Veterinary medicinal product subject to prescription.