

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 of 1 ml contains:

Active substances:

Influenza A/eq/Ohio/03 [H₃N₈] recombinant Canarypox virus (vCP2242)≥ 5.3 log₁₀ FAID₅₀*

Influenza A/eq/Richmond/1/07 [H₃N₈] recombinant Canarypox virus (vCP3011)≥ 5.3 log₁₀ FAID₅₀*

Clostridium tetani toxoid≥ 30 IU**

* vCP content checked by global FAID₅₀ (fluorescent assay infectious dose 50 %) and qPCR ratio between vCP.

** antitoxic antibody titre induced after repeated vaccination in guinea pig sera according to Ph. Eur.

Adjuvant:

Carbomer 4 mg.

For the 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 which usually regresses within 4 days may appear at the injection site. In rare occasions, swelling can reach a diameter up to 15–20 cm, with duration up to 2–3 weeks, that may require symptomatic treatment.
- Pain, local hyperthermia and muscle stiffness can occur in rare cases.
- In very rare occasions, abscessation may be observed.
- 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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 vCP3011 are recombinant canarypox viruses expressing the haemagglutinin *HA* gene from the equine influenza virus strains A/eq/Ohio/03 (American strain, Florida sublineage clade 1) and A/eq/Richmond/1/07 (American strain, Florida sublineage clade2), 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 (H₃N₈).

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

Shelf life of the veterinary medicinal product as packaged for sale: 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

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 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. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE**
- C. STATEMENT OF THE MRLs**
- D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substances

Influenza component:

MERIAL

Laboratoire Porte des Alpes

Rue de l'Aviation

69800 Saint Priest

FRANCE

MERIAL

Laboratory of Lyon Gerland

254, Avenue Marcel Mérieux

69007 Lyon

FRANCE

Tetanus component:

MERIAL Toulouse

4, chemin du Calquet

31057 Toulouse Cedex

FRANCE

Name and address of the manufacturer responsible for batch release

MERIAL

Laboratoire Porte des Alpes

Rue de l'Aviation

69800 Saint Priest

FRANCE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substances being a principle of biological origin intended to produce active immunity are 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 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 product.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

The periodic safety update report (PSUR) cycle would be re-started for submission of 6 monthly reports (covering all authorised presentations of the product) for the next two years, followed by yearly reports for the subsequent two years and thereafter at three-yearly intervals.

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 of 1 ml contains:

Active substances:

Influenza A/eq/Ohio/03 [H₃N₈] (vCP2242) ≥ 5.3 log₁₀ FAID₅₀
Influenza A/eq/Richmond/1/07 [H₃N₈] (vCP3011) ≥ 5.3 log₁₀ FAID₅₀
Clostridium tetani toxoid ≥ 30 IU

Adjuvant:

Carbomer 4 mg.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10x1 ml (10 doses).

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

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/2/03/038/005

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
69007 Lyon
FRANCE

Manufacturer for the batch release:

MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
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 of 1 ml contains:

Active substances:

Influenza A/eq/Ohio/03 [H₃N₈] recombinant canarypox virus (vCP2242) ≥ 5.3 log₁₀ FAID₅₀*

Influenza A/eq/Richmond/1/07 [H₃N₈] recombinant canarypox virus (vCP3011) ≥ 5.3 log₁₀ FAID₅₀*

Clostridium tetani toxoid ≥ 30 IU**

* vCP content checked by global FAID₅₀ (fluorescent assay infectious dose 50 %) and qPCR ratio between vCP.

** 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 which usually regresses within 4 days may appear at the injection site. In rare occasions, swelling can reach a diameter up to 15–20 cm, with duration up to 2–3 weeks, that may require symptomatic treatment.
- Pain, local hyperthermia and muscle stiffness can occur in rare cases.
- In very rare occasions, abscessation may be observed.
- 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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 sight and reach 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)

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.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

No interaction has been observed when the vaccine was administered simultaneously, but at a separate site, with MERIAL's inactivated vaccine against rabies.

Overdose (symptoms, emergency procedures, antidotes):

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

Incompatibilities:

Do not mix with any veterinary medicinal product.

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

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 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 vCP3011 are recombinant canarypox viruses expressing the haemagglutinin *HA* gene from the equine influenza virus strains A/eq/Ohio/03 (American strain, Florida sublineage clade 1) and A/eq/Richmond/1/07 (American strain, Florida sublineage clade 2), 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 (H₃N₈).

Box of 10 vials of 1 dose.

Veterinary medicinal product subject to prescription.