1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip FT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains: Equine influenza virus inactivated strains:

Active substances:

A/Equine/Newmarket/77 (H7N7)	$\geq 1.2 \log_{10}$ HAI*
A/Equine/Borlange/91 (H3N8)	$\geq 2.1 \log_{10}$ HAI*
A/Equine/Kentucky/98 (H3N8)	$\geq 2.4 \log_{10}$ HAI*
Immunopurified Tetanus Toxoid	≥ 70 IU/ml**

*HAI: Haemagglutination inhibition titre
**IU: International units

Adjuvants:
Quillaic Acid derivative (Quil A)
Aluminium phosphate

Excipients:

Qualitative composition of excipients and other constituents
Phosphatidyl choline
Cholesterol
Ammonium acetate
Phosphate buffered saline

Clear liquid suspension above a whitish grey sediment which resuspends readily on shaking.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the active immunisation of horses of 5 months of age or older against Equine Influenza of H7N7 and H3N8 types (European or American strains, including Florida sublineage Clade 1 and Clade 2 isolates) to reduce clinical signs and virus excretion after infection, and against tetanus to prevent mortality.

Onset of immunity: within 2 weeks of completion of the primary course.
Duration of immunity: 15 months for influenza and 3 years for tetanus.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The efficacy of active immunisation of young foals against equine influenza and tetanus will be influenced by the level of maternally derived antibodies. This will vary between individuals due to a number of factors, e.g. the immune status of the dam; adequacy of colostral intake by the foal, etc. The vaccine should not be used in foals below 5 months of age, and foals should not be vaccinated until maternally derived antibodies have fallen below protective levels.

In any animal population, there may be a small number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon correct storage and administration of the vaccine and the ability of the animal to respond. This can be influenced by such factors as genetic constitution, intercurrent infection, age, nutritional status, concurrent drug therapy and stress.

3.5 Special precautions for use

Special precautions for safe use in the target species:

None.

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

The veterinary medicinal product should be administered by respecting appropriate (aseptic) injection technique.

In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Rare (1 to 10 animals / 10,000 animals treated):	Injection site swelling[1,3] Stiffness[1] Elevated temperature[1,2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain Hypersensitivity reaction (Anaphylactic-type reaction)[4] Anorexia, Lethargy

[1] Normally resolves by the day following vaccination.
[2] Mild, transient, typically 9-12 hours post vaccination.
[3] Soft and non-painful measuring 10-20 mm in diameter.
[4] In the event of an allergic or anaphylactic reaction, immediate treatment should be given with a soluble glucocorticoid intravenously or adrenalin intramuscularly.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used in pregnant mares which have been vaccinated against both influenza and tetanus before pregnancy.
Heavily pregnant mares should not be subject to undue stress when vaccinated.

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

Intramuscular use.

Dose: 2 ml.

Administration: The veterinary medicinal product should be shaken thoroughly before use, and administered by deep intramuscular injection.

Vaccination schedule: For protection against equine influenza and tetanus, the veterinary medicinal product should be used as follows:

Primary course	First dose	EQUIP FT
		6 week interval
	Second dose	EQUIP FT
		5 month interval
Boosters	1st booster	EQUIP F
		12-15 month interval
	2nd booster	EQUIP F
		12-15 month interval
	3rd booster	EQUIP FT

Thereafter, booster doses of Equip FT or Equip F should be administered so that the
interval between vaccinations against influenza is no more than 15 months and the interval between vaccinations against tetanus is not more than 36 months.
Note: The routine practice of administering booster doses against influenza annually may remain the most convenient, even though protection against equine influenza has been demonstrated by challenge studies 15 months following the third vaccination (first booster dose). No field challenge studies have been carried out prior to the third vaccination; instead efficacy was evaluated by serology which showed titres equivalent to those found in horses protected against challenge at 15 months. It is recommended that a single booster dose should only be administered to horses that have already received a full primary course using vaccines that contain the same types of equine influenza virus included in this vaccine. A full primary course may be considered necessary in horses that have not been suitably primed.

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

Accidental overdosage is unlikely to cause any reactions other than those described in section 3.6.

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

Meat and offal: zero days.
Not authorised for use in animals producing milk for human consumption.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI05AL01

The veterinary medicinal product stimulates active immunity against equine influenza virus and tetanus by eliciting both a cell mediated immune response and a humoral response.

Further information on the protection afforded by vaccination:
Onset of immunity has been demonstrated by virulent challenge for Equine Influenza strains A/equine/Newmarket/1/93 (American lineage H3N8), A/equine/South Africa/4/03 (Florida sublineage Clade 1 of the American lineage H3N8), A/equine/Sydney/2888-8/07 (Florida sublineage Clade 1 of the American lineage H3N8) and A/equine/Richmond/1/07 (Florida sublineage Clade 2 of the American lineage H3N8).
Duration of immunity has been demonstrated by virulent challenge for Equine Influenza strains A/equine/Sussex/89 (Eurasian lineage H3N8) and A/equine/Newmarket/2/93 (Eurasian lineage H3N8).
Protection afforded by vaccination is additionally demonstrated by serology for Equine Influenza strains A/equine/Newmarket/77 (H7N7), A/equine/Brentwood/79 (Eurasian lineage H3N8), A/equine/Borlange/91 (Eurasian lineage H3N8), A/equine/Kentucky/98 (American lineage H3N8), A/equine/Newmarket/1/93 (American lineage H3N8), A/equine/Newmarket/2/93 (Eurasian lineage H3N8), A/equine/South Africa/4/03 (Florida sublineage Clade 1 of the American lineage H3N8), A/equine/Sydney/2888-8/07 (Florida sublineage Clade 1 of the American lineage H3N8) and A/equine/Richmond/1/07 (Florida sublineage Clade 2 of the American lineage H3N8).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Keep the container in the outer carton.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass vial with chlorobutyl rubber stopper and aluminium overseal.
Packaging: Box of 10 single-dose vials. Each box contains 10 sterile disposable 2 ml syringes and 10 sterile needles.

Type I glass syringe closed with bromobutyl rubber plunger stopper and tip cap.
Packaging: Box of 10 single-dose prefilled syringes with needles.

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER

VPA10387/030/001

8. DATE OF FIRST AUTHORISATION

04/07/2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

30/04/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).