1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip F.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Equine influenza virus inactivated strains:Quantity per dose (2 ml)
A/equine/Newmarket/77 (H7N7)≥ 1.2 log_{10}HAI*

A/equine/Borlange/91(H3N8)≥ 2.1 log_{10}HAI*
A/equine/Kentucky/98 (H3N8)≥ 2.4 log_{10}HAI*

*HAI: Haemagglutination inhibition titre

Adjuvant(s):
Quil A
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses from 5 months of age

4.2 Indications for use, specifying the target species

For the active immunisation of horses of 5 months of age or older against Equine Influenzaof 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.

Duration of immunity is at least 15 months.
Onset of immunity is within 2 weeks of completion of the primary course.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The efficacy of active immunisation of young foals against equine influenza 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.

4.5 Special precautions for use

Special precautions for use in animals

Do not use in unhealthy animals.
The product should be administered by respecting appropriate (aseptic) injection technique.

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)

Rarely (<1 in 1000), animals may exhibit a reaction to vaccination. This may be manifest by stiffness, a mild, transient rise in temperature, typically 9-12 hours post vaccination, or a small soft, non-painful local swelling (10-20 mm in diameter) at the injection site. These conditions normally resolve by the day following vaccination.

Injection site pain, anorexia and lethargy have been reported in very rare cases (<1 in 10,000).

Occasional hypersensitivity reactions may occur. In the event of an allergic or anaphylactic reaction, immediate treatment should be given with a soluble glucocorticoid intravenously or adrenalin intramuscularly.

4.7 Use during pregnancy, lactation or lay

The vaccine may be used in pregnant mares which have been vaccinated against influenza before pregnancy. Heavily pregnant mares should not be subject to undue stress when vaccinated.

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

Dose: 2 ml
Administration: Equip F should be shaken thoroughly before use, and administered by deep intramuscular injection.
Vaccination Regime: For protection against equine influenza, Equip F should be used as follows:

Primary Course	
First dose	EQUIP F 6 week interval
Second dose	EQUIP F 5 month interval
Boosters	
1st booster	EQUIP F 12-15 month interval
2nd and subsequent boosters	EQUIP F 12-15 month intervals

Note: The routine practice of administering booster doses 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.

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

Accidental overdose is unlikely to cause any reactions other than those described in section 4.6.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Equip F stimulates active immunity against equine influenza virus 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 lineageH3N8), A/equine/Borlange/91 (Eurasian lineageH3N8), 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).

ATC Vet Code: QI05AA01

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Quillaic Acid derivative (Quil A)

Phosphatidyl choline
Cholesterol
Ammonium acetate
Phosphate buffered saline

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: 3 years

6.4 Special precautions for storage

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

6.5 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 ten sterile disposable 2ml 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.

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 products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/029/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th December 2002
Date of last renewal: 5th December 2011

10 DATE OF REVISION OF THE TEXT

October 2017