

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip F suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:

Equine influenza virus inactivated strains:

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*

* HAI: Haemagglutination Inhibition titre

Adjuvant:

Quil A

Excipients:

Qualitative composition of excipients and other constituents
Quillaic Acid derivative (Quil A)
Phosphatidyl choline
Cholesterol
Ammonium acetate
Phosphate buffered saline

Slightly opalescent solution.

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.

Onset of immunity: within 2 weeks of completion of the primary course
Duration of immunity: 15 months.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the 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.

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

The 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.

Other precautions:

Not applicable.

3.6 Adverse events

Horses.

Rare (1 to 10 animals / 10,000 animals treated):	Injection site swelling ^{1,3} Stiffness ¹ Elevated temperature ^{1, 2}
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Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain Hypersensitivity reaction ⁴ Anorexia, Lethargy
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¹ This condition normally resolves by the day following vaccination.

² Mild, transient, typically 9-12 hours post vaccination.

³ Local, small (10-20 mm in diameter), soft, non-painful.

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:

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.

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

Dose: 2 ml.

Administration: Equip F should be shaken thoroughly before use, and administered by deep intramuscular injection.

Vaccination schedule: For protection against quine 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	1 st booster	EQUIP F 12-15 month interval
2 nd 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.

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

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI05AA01

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 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).

Protect from light.

Do not freeze.

Keep the container in the outer carton.

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 syringes 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 product 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 UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/4061

8. DATE OF FIRST AUTHORISATION

17 October 2005

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

January 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved 04 March 2025