SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip T

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 2ml:

Active substances:
Immunopurified Tetanus Toxoid ≥ 30 IU/ml[$]

[$] IU: International units

Adjuvant:
Aluminium phosphate

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 tetanus to prevent mortality.
Duration of immunity is at least 36 months.
Onset of immunity is within 2 weeks of completion of the primary course.

4.3 Contraindications

None.

4.4 Special warnings

The efficacy of active immunisation of young foals against 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 on 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

i) Special precautions for use in animals

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

ii) 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 has 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 tetanus 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 T should be shaken thoroughly before use and administered by deep intramuscular injection.
Primary vaccination
Two injections of 2 ml with an interval of 4-6 weeks between them.
Booster vaccination
One dose 36 months after the primary course, repeated at intervals of up to 36 months.

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

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

4.11 Withdrawal period

Zero days

5. IMMUNOLOGICAL PROPERTIES

Equip T stimulates active immunity against tetanus.

ATCVet Code: QI05AB03

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium phosphate
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 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.

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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4064

9. DATE OF FIRST AUTHORISATION

17 October 2005

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 19 August 2020