ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 x 2 ml dose Folding Carton
10x 2ml dose Booklet Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip T

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (2 ml) contains concentrated immunopurified tetanus toxoid (100 Lf units) adsorbed onto aluminium phosphate.

3. PHARMACEUTICAL FORM

Suspension for Injection
Tetanus Vaccine

4. PACKAGE SIZE

10 x 2 ml doses

5. TARGET SPECIES

For the vaccination of healthy horses from 5 months of age against tetanus.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: 2ml
Administer by deep intramuscular injection.
See package leaflet for vaccination programme and warnings.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

IMPORTANT: Read the instructions before use.

10. EXPIRY DATE

Exp date {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

UK Only: **MA Holder:** Zoetis UK Limited 1st Floor, Birchwood Building Springfield Drive Leatherhead Surrey KT22 7LP POM-V To be supplied only on Veterinary prescription	**IE Only:** **VPA Holder:** Zoetis Ireland Limited 25/28 North Wall Quay Dublin 1 POM Prescription only medicine

16. MARKETING AUTHORISATION NUMBER(S)

UK Only:
Vm 42058/4064

IE Only:
VPA 10438/51/1

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

2 ml Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip T
Suspension for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains concentrated immunopurified tetanus toxoid (100 Lf units/dose).

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2ml (1 dose)

4. ROUTE(S) OF ADMINISTRATION

For deep intramuscular injection. Shake well before use

5. WITHDRAWAL PERIOD

Withdrawal period: zero days

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expiry date:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Read pack leaflet before use.
Keep the container in the outer carton.

UK: Vm 42058/4064 POM-V
IE: VPA 10438/51/1 POM

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Single dose syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip T Suspension for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Equine Tetanus Vaccine

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Equip T

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

UK Only: **MA Holder:** Zoetis UK Limited 1st Floor, Birchwood Building Springfield Drive Leatherhead Surrey KT22 7LP Vm 42058/4064 POM-V To be supplied only on Veterinary prescription	**IE Only:** **VPA Holder:** Zoetis Ireland Limited 25/28 North Wall Quay Dublin 1 VPA 10438/51/1 POM Prescription only medicine

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burnait
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip T
Suspension for injection
Tetanus Vaccine

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 2 ml dose of the vaccine contains immunopurified tetanus toxoid (100 Lf units) adsorbed onto aluminium phosphate.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

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.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses from 5 months of age

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose: 2ml

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

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2°C to 8°C).
Protect from light. Do not freeze.
Keep out of the sight and reach of children.
Keep the container in the outer carton.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

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 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 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.

Use during pregnancy and lactation:
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.

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.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
Accidental overdosage is unlikely to cause any reactions other than those described under Adverse Reactions above.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

For animal treatment only.
Equip T stimulates active immunity against tetanus.

Ph Eur Type I neutral glass vials 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.

Ph Eur Type I neutral glass syringes with bromobutyl rubber stopper and aluminium overseal.
Packaging: Box of 10 single-dose prefilled syringes with needles

Not all pack sizes may be marketed.

Approved 19 August 2020