ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

E. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) of the biological active substance(s)
Zoetis Manufacturing & Research Spain, S.L
C/Camprodon s/n “La Riba”
17813 Vall de Bianya
Girona
Spain

Name and address of the manufacturer(s) responsible for batch release
Zoetis Manufacturing & Research Spain, S.L
C/Camprodon s/n “La Riba”
17813 Vall de Bianya
Girona
Spain

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

E. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{1 x 1,000 dose, 1 x 2,000 dose, 1 x 5,000 dose, 10 x 1,000 dose, 10 x 2,000 dose, 10 x 5,000 dose}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac TRT Vaccine, lyophilisate for suspension for spray, eye drop or nose drop administration for turkeys.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Turkey rhinotracheitis virus, strain clone K $10^{3.2}$ - $10^{4.5}$ *$CCID_{50}$ /ds
* $CCID_{50}$ = Cell Culture Infectious Dose 50%

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for spray, eye drop or nose drop administration.

4. PACKAGE SIZE

1 x 1,000 doses, 1 x 2,000 doses, 1 x 5,000 doses 10 x 1,000 doses, 10 x 2,000 doses, 10 x 5,000 doses

5. TARGET SPECIES

Turkeys.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: 0 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once reconstituted use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze. Protect from light.
Keep the container in the outer carton.

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

Disposal: read package leaflet.

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

For animal treatment only.

To be supplied only on veterinary prescription.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4113

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS

1,000 dose, 2,000 dose, 5,000 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac TRT Vaccine, lyophilisate for suspension for spray, eye drop or nose drop administration for turkeys.

2. QUANTITY OF THE ACTIVE SUBSTANCES

Attenuated turkey rhinotracheitis virus, strain clone K vaccine ($10^{3.2}$ - $10^{4.5}$ $CCID_{50}$ per dose).

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

1,000 doses, 2,000 doses, 5,000 doses

4. ROUTE OF ADMINISTRATION

Spray, eye drop or nose drop administration.

5. WITHDRAWAL PERIOD

Withdrawal period: 0 days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Poulvac TRT vaccine, lyophilisate for suspension for spray, eye drop or nose drop administration for turkeys.

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

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain, S.L
Ctra. Camprodon s/n "La Riba"
17813 Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac TRT Vaccine, lyophilisate for suspension for spray, eye drop or nose drop administration for turkeys.

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

One dose contains:

Active substance:
Attenuated turkey rhinotracheitis virus, strain clone K $10^{3.2}$ - $10^{4.5}$ *$CCID_{50}$

* $CCID_{50}$ = Cell Culture Infectious Dose 50%

Cream coloured lyophilisate.

4. INDICATION(S)

For active immunisation of turkeys to reduce clinical signs associated with infection with TRT.
Onset of immunity: Immunity to challenge has been demonstrated 3 weeks after vaccination
Duration of immunity: 14 weeks.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

In rare cases, turkeys may display mild TRT symptoms (i.e. nasal exudate) from day 7 to 8 post vaccination.
In field trials, reactions of a transient nature lasting 1-2 days were seen rarely between day 10 and 21 post vaccination.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Turkeys

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

One dose per bird from one day of age to be administered by coarse spray.

Spray
The vaccine should be reconstituted with water of good quality at room temperature, e.g. deionised water or good quality drinking water. Treat water with milk powder if necessary but ensure there are no particles which may block the spray nozzle. Remove the aluminium seal from the vaccine vial. To dissolve the vaccine pellet, the rubber stopper should be removed whilst the vial is immersed in a clean plastic measuring jug containing 0.2-0.5 litre of water (as noted below for sprayer types). Half fill the vial with water, replace the stopper and shake to dissolve any remaining vaccine.
Pour into the jug and stir carefully to ensure even dispersal of the vaccine.
The vaccine should then be added to the sprayer.
The quantity of water depends on the method of administration:
Hand spray: 0.2 L/1,000 birds
Knapsack spray: 0.5 L/1,000 birds, if the birds are housed on the ground.
0.25 L/1,000 birds, if the birds are housed in a battery.
Automatic spray equipment: 0.15-0.50 L/1,000 birds (hatchery)
Spray equipment, providing a droplet size of 0.12 - 0.15 mm has to be used (hand spray, knapsack spray, automatic spray equipment). The distance from the spraying head to the birds must be approximately 50 cm. Hold birds in boxes for approximately 30-45 minutes. Ensure the temperature of the holding area is 70-80°F and draught free, to avoid chilling.
Spray application is only to be carried out in housings which can be closed properly. Turn off ventilation fans, if any, to avoid air movement.

Eye drop/nose drop

30-50 ml/1000 birds, 0.03-0.05 ml/eye or nostril.

Reconstitute vaccine by dissolving in deionised water for eye drop at the rate of 30 ml to 1,000 doses. The deionised water should be at room temperature. Remove the aluminium cap and rubber stopper from the vaccine vial and add deionised water from 30 ml to half fill the vial. Replace the rubber stopper and shake so that all the vaccine material is completely dissolved. Pour the vaccine concentrate into the rest of the 30 ml and mix well.

Administer by dropper at the rate of one drop (0.03 ml) per bird onto one eye. The use of standardised droppers is recommended. Hold the bird so that one eye is pointing upwards and allow one drop of vaccine to fall into the eye. Birds should swallow during vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

Only disinfectant-free and/or antiseptic free materials should be used for the preparation of vaccine solution.

10. WITHDRAWAL PERIOD

Zero Days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2ºC - 8ºC). Protect from light. Do not freeze.
Keep the container in the outer carton.

Shelf-life after reconstitution according to directions: 4 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the vial.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

The use of the vaccine in turkeys older than 10 days does not induce sufficient protection due to the resistance against TRT increasing with age.

Special precautions for use in animals:
In order to prevent risks of dissemination of the vaccine in the site, all the birds at the same site should be correctly vaccinated.

Do not vaccinate in mixed breeding farms where turkeys and other avian species, except chickens, are raised. The virus contained in the vaccine was shown to spread for approximately 10 days. This spreading appeared to be without any consequence for chickens.

Th is a possibility that the virus may be disseminated to other avian species and care should be taken to avoid contact with other birds.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
If the vaccine is administered by spray, personal protective equipment consisting of safety goggles and a dust mask or a helmet with filtered air circulation should be worn.

Lay:
Do not use in turkeys in lay.

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):
Administration of a 10 fold overdose does not result in significantly worse adverse reactions to those seen after administration of a single dose.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except diluents or other component recommended for use with the veterinary medicinal product.

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2021

15. OTHER INFORMATION

For Animal Treatment Only

ATC Vet Code: QI01CD01

PACKAGE QUANTITIES

Pack sizes:
Cardboard boxes containing 1 vial of 1,000 doses
Cardboard boxes containing 1 vial of 2,000 doses
Cardboard boxes containing 1 vial of 5,000 doses
Cardboard boxes containing 10 vials of 1,000 doses
Cardboard boxes containing 10 vials of 2,000 doses
Cardboard boxes containing 10 vials of 5,000 doses

Not all pack sizes may be marketed.

LEGAL CATEGORY

To be supplied only on veterinary prescription

MARKETING AUTHORISATION NUMBER

Vm 42058/4113

Approved 29 July 2021