PARTICULARS TO APPEAR ON THE OUTER PACKAGE (500 doses, 1000 doses and 10x 5000 doses cartons)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tur-3

0.3 ml/dose

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated Newcastle Disease virus (at least 50 PD_{50}*), Turkey Rhinotracheitis virus (at least 9 EU) and Paramyxovirus Type 3 virus (at least 40 HAIU) in an oily adjuvant.

Contains paraffin oil (170 to 186 mg) and thiomersal (15 µg).

*50 PD_{50} (50% protective dose) is performed in chickens.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

500 doses
Vial containing 150 ml

1000 doses
1 vial containing 300ml

5000 doses
10 vials containing 150ml

5. TARGET SPECIES

Turkeys

6. INDICATION(S)

Inactivated vaccine for turkey breeders.

Stimulates active immunity in turkeys against Paramyxovirus Type 3 and, subsequent to priming with live vaccines against Newcastle Disease and Turkey Rhinotracheitis, active immunity against Newcastle Disease and Turkey Rhinotracheitis

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection.

8. WITHDRAWAL PERIOD

Withdrawal period: zero hours/days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous; see package leaflet.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Store between +2°C and +8°C.
Protect from light. Do not freeze.
Do not keep partly used containers - use immediately after opening.

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

See package leaflet for further information.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4134

17. MANUFACTURER'S BATCH NUMBER

Batch:

18. FURTHER INFORMATION

To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (500 and 1000 dose labels)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tur-3

0.3 ml/dose

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated Newcastle Disease virus (at least $50PD_{50}$*), Turkey Rhinotracheitis virus (at least 9 EU) and Paramyxovirus Type 3 virus (at least 40 HAIU) in an oily adjuvant.

Contains paraffin oil (170 to 186 mg) and thiomersal (15 µg).

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

500 dose vial
1000 dose vial

5. TARGET SPECIES

Turkeys

6. INDICATION(S)

Stimulates active immunity in turkeys against Paramyxovirus Type 3 and, subsequent to priming with live vaccines against Newcastle Disease and Turkey Rhinotracheitis, active immunity against Newcastle Disease and Turkey Rhinotracheitis

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection.

8. WITHDRAWAL PERIOD

Withdrawal period: zero hours/days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous; see package leaflet.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Protect from light. Store between +2°C and +8°C. Do not freeze.
Keep the container in the outer carton.

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

See package leaflet for further information.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4134

17. MANUFACTURER'S BATCH NUMBER

Batch:

18. FURTHER INFORMATION

To be supplied only on veterinary prescription.

PACKAGE LEAFLET FOR: Tur-3

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

Marketing Authorisation Holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tur-3

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

An inactivated vaccine prepared from Paramyxovirus Type 3 (at least 40 HAIU), Newcastle Disease virus (at least 50 PD_{50}*) and Turkey Rhinotracheitis virus (at least 9 EU) in an oily adjuvant.

Contains paraffin oil (170 to 186 mg) and thiomersal (15 µg).

* 50 PD_{50} (50% protective dose) is performed in chickens.

4. INDICATION(S)

For active immunisation of future breeder turkeys:
- as booster vaccination after priming with live vaccines against Newcastle Disease and Turkey Rhinotracheitis to reduce mortality and clinical signs of Newcastle Disease and to induce a specific seroconversion against Newcastle Disease and Turkey Rhinotracheitis in vaccinated birds throughout the laying period
- as vaccination against Paramyxovirus Type 3 to reduce the decrease in egg production, as demonstrated by challenge at peak lay, and to induce a specific seroconversion against Paramyxovirus Type 3 throughout the laying period.

Onset of immunity: 4 weeks after the first injection.
Duration of immunity: one laying period (demonstrated by serology).

5. CONTRAINDICATIONS

Do not vaccinate unhealthy birds.
Apply the usual aseptic precautions.
Do not use syringes with natural rubber or butyl elastomer pistons.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Turkeys.

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

One 0.3 ml dose given by intramuscular injection.
Primary vaccination: One injection 8 - 10 weeks before onset of lay.
Booster vaccination: One injection 2 - 4 weeks before onset of lay.

9. ADVICE ON CORRECT ADMINISTRATION

Remove from the refrigerator and allow to reach room temperature before using. Shake well before use.

Tur-3 may be used with automatic vaccinating equipment. Equipment including needles and syringes must be sterile before use.

10. WITHDRAWAL PERIOD

Zero hours/days.

11. SPECIAL STORAGE PRECAUTIONS

Store between +2°C and +8°C, protected from light. Do not freeze. Check expiry date before use.
Do not keep partly used containers - use immediately after opening.

12. SPECIAL WARNINGS

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 decided on a case by case basis.
Do not mix with any other veterinary medicinal product.

Operator Warnings

To the user:
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling which may, for example, result in ischemic necrosis and even loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.
For Animal Treatment Only.

Keep out of reach of children.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Legal category

POM-V

To be supplied only on veterinary prescription.

Package quantities
500-dose (polypropylene) bottle.
500-dose (polypropylene) bottle, box of 10 bottles.
1000-dose (polypropylene) bottle.
1000-dose (polypropylene) bottle, box of 10 bottles.

Not all pack sizes may be marketed.

Further information
The vaccine induces a specific serological response against Newcastle disease, Turkey Rhinotracheitis and Paramyxovirus type 3, in vaccinated birds that persists for 21 weeks post completion of the vaccination course. Studies have demonstrated that the vaccine can be used as an aid in the prevention of 'egg drop' caused by Paramyxovirus Type 3 challenge.

This product is not recommended for administration to birds 'in lay'.

This is a Limited Marketing Authorisation and the limitations of the product are reflected in the claims.

All suspected adverse reactions and any suspected lack of efficacy should be reported to 01344 746957 at Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK.

Further information on this product and its supporting data can be found on http://www.vmd.gov.uk/ProductInformationDatabase.

Marketing Authorisation N° Vm 08327/4134

Approved: 07 January 2019

D Austin