SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TUR-3

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Inactivated Paramyxovirus Type 3, at least ……40 HAIU
Inactivated Newcastle Disease virus, at least ……50 PD_{50}
Inactivated Turkey Rhinotracheitis virus, at least…….. 9 EU

Adjuvant:
Paraffin oil……170 to 186 mg

Excipient:
Thiomersal…..…… 15 µg

1 HAIU: q.s. to obtain a mean haemagglutination inhibiting antibody titre of 1 in vaccinated animals
1 EU: q.s. to obtain a positive serum by ELISA in one vaccinated animal
50 PD_{50} (50% protective dose) is performed in chickens.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Future breeder turkeys.

4.2 Indications for use, specifying the target species

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).

4.3 Contra-indications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

Vaccinate only healthy animals.
Apply usual aseptic procedures.
Do not use syringes with natural rubber or butyl elastomer pistons.
Do not keep partly used containers - use immediately after opening. 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.

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

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 ischaemic 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.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

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

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 decided on a case by case basis.

4.9 Amounts to be administered and administration route

Posology:

One 0.3-ml dose.

Method and route of administration:

Shake well before use.
Intramuscular route.
Primary vaccination: one injection 8 to 10 weeks before the beginning of lay.
Booster vaccination: one injection 2 to 4 weeks before the beginning of lay.

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

In the double dose overdose study no abnormal local or systemic reactions occurred.

4.11 Withdrawal periods

Zero hours/days.

5. IMMUNOLOGICAL PROPERTIES

The vaccine induces a specific serological response against Newcastle disease, Turkey Rhinotracheitis and Paramyxovirus Type 3, in vaccinated animals 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.

ATC Vet Code:

QI01CA02

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Paraffin oil
Ester of fatty acids and polyols

6.2 Major 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: 24 months.

6.4 Special precautions for storage

Store between +2°C and +8 °C, protected from light. Do not freeze.

Once broached, use immediately.

6.5 Nature and composition of immediate packaging

500-dose (polypropylene) bottle.
500-dose (polypropylene) bottle, 10 bottle package.
1,000-dose (polypropylene) bottle.
1,000-dose (polypropylene) bottle, 10 bottle package.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4134

9. DATE OF FIRST AUTHORISATION

23 May 1997

10. DATE OF REVISION OF THE TEXT

November 2018

ADDITIONAL INFORMATION

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., Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, UK.

Further information on this product and its supporting data can be found on **HTTP://WWW.VMD.GOV.UK/PRODUCTINFORMATIONDATABASE**.

Approved: 07 January 2019