Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

TUR-3 emulsion for injection for turkeys

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of vaccine contains:

Active substances:

Paramyxovirus 3, inactivated strain PMV3, at least	40 HI.U
Newcastle Disease virus, inactivated strain Ulster 2C, at least	50 PD50
Turkey rhinotracheitis virus, inactivated, strain VCO3, at least	9 ELISA.U

Adjuvant:

Paraffin oil	170 to186 mg
Ester of fatty acids and polyols	6 to 15 mg

For a full list of excipients, see section 6.1.

1 HIU: q.s. to obtain a mean haemagglutination inhibiting antibody titre of 1 in the vaccinated animal

PD50: Minimum protective dose in accordance with Ph.Eur. 870.

1 ELISA U.: q.s. to obtain a positive serum by ELISA in the vaccinated bird

3 PHARMACEUTICAL FORM

Emulsion for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Turkeys intended for breeding.

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 of lay, and to induce a specific seroconversion against paramyxovirus type 3 throughout the laying period.
Onset of immunity: 4 weeks after the first dose of the vaccination schedule. The second dose is required to achieve protection for the specified duration of immunity.Duration of immunity: one laying period (demonstrated by serology).

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy birds.

Special precautions to be taken by the person administering the veterinary medicinal product to 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 orfinger, 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 the 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)

No palpable reactions were observed following the injection of one dose of vaccine. However, lesions linked to the oily adjuvant may be observed histologically.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay or within 2 weeks before the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interactions

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

Turkeys (aged 2 weeks or older) intended for breeding.
For intramuscular administration.
One dose: 0.3 ml

Vaccination schedule:

Dose 1: 8 to 10 weeks before the beginning of lay and at least 4 weeks after the priming with live vaccines against Newcastle Disease and Turkey Rhinotracheitis.
Dose 2: 2 to 4 weeks before the beginning of lay.

Revaccination schedule:
Dose 3 andsubsequent doses: 2 to 4 weeks before the beginning of each lay.

Shake well before use. Do not use syringes with natural rubber or butyl elastomer pistons.

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

No undesirable effect except those mentioned in paragraph 'Adverse reactions (frequency and seriousness)' was observed.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The vaccine stimulates active immunity of future breeder turkeys against Newcastle Disease, paramyxovirus type 3 and infectious rhinotracheitis in turkeys, subsequent to priming with live vaccines against Newcastle Disease and infectious rhinotracheitis in turkeys.
ATC vet code: QI01CA02

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal

Ester of fatty acids and of ethoxylated polyols

Water for injection

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.
Shelf-life after first opening the immediate packaging***:*** Use immediately after opening.

6.4 Special precautions for storage

Store and transport refrigerated 2°C - 8°C.
Protect from light.

6.5 Nature and composition of immediate packaging

Nature of containers:

Polypropylene bottle, nitrile elastomer closure and aluminium cap.

Contents:
Box with one 500 dose bottle.
Box with ten 500 dose bottles.
Box with one 1,000 dose bottle.

Box with ten 1,000 dose bottles.
Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/078/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st December 2006
Date of last renewal: 4th November 2011

10 DATE OF REVISION OF THE TEXT

May 2018