1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gallimune 303 ND+IB+ART emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.3 ml dose contains:

Active substances:
Inactivated Newcastle disease virus, Ulster 2C strain, at least.....50 PD_{50}[1]
Inactivated infectious bronchitis virus, Mass41 strain, at least .....18 HI.U
Inactivated turkey rhinotracheitis virus[2], VCO3 strain, at least ..... 0.76 ODD
The concentrations are expressed by the antibody titre obtained during the potency test. One unit (U) corresponding to an antibody titre of 1.
HI: haemagglutination inhibiting - ODD : optical density difference
[1] Minimum protective dose according to monograph 0870 of Ph. Eur.
[2] Previously referred to as avian rhinotracheitis (ART) virus which is the triggering pathogen in swollen head syndrome in chickens.

Adjuvant:
Paraffin oil.....170 to 186 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	30 µg
Formaldehyde	at most 45 µg
Ester of fatty acids and of polyols	
Ester of fatty acids and of ethoxylated polyols	
Water for injections	

Whitish homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (breeder and layer pullets).

3.2 Indications for use for each target species

Booster immunisation of breeder and layer pullets after vaccination with live vaccines against:
- Newcastle disease virus in order to reduce egg drop linked to Newcastle disease infection,
- Infectious bronchitis virus in order to reduce egg drop linked to infectious bronchitis infection caused by the Mass 41 strain,
- Avian pneumovirus in order to reduce respiratory signs linked to avian pneumovirus infection (swollen head syndrome).

Newcastle disease and infectious bronchitis components:

- Onset of immunity: 4 weeks after vaccination,
- Duration of immunity: one laying period.

Turkey rhinotracheitis component:
- Onset of immunity: 14 weeks after vaccination,
- Duration of immunity: one laying period.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This veterinary medicinal 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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Abnormal histology[1]

[1] Lesions at the injection site, linked to the oily adjuvant were observed histologically three weeks after injections in 87 % of cases, e.g. small quantities of oily residues and occasional aseptic micro-abscesses. No palpable reactions were observed.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing

authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Do not use in birds in lay and within 4 weeks before the start of the laying period.

3.8 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 made on a case by case basis.

3.9 Administration routes and dosage

Administer one dose (0.3 ml) by intramuscular route from the age of 18 weeks and at least 4 weeks after the priming with live vaccines against Newcastle disease (strain Hitchner B1 or VG/GA-AVINEW), infectious bronchitis (strain Mass H120), and avian pneumovirus (strain PL21).

Shake well before use.
Apply usual aseptic procedures.
Do not use syringes with natural rubber or butyl elastomer pistons.
Equipment including needles and syringes must be sterile before use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Transitory apathy and slight oedema at injection site may occur after the administration of a double dose of vaccine.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATC vet code: QI01AA21

Inactivated vaccine in oily adjuvant against Newcastle disease, infectious bronchitis and swollen head syndrome.

The vaccine stimulates active immunity of breeder and layer pullets against Newcastle disease, infectious bronchitis and swollen head syndrome, subsequent to priming with live vaccines against these diseases.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Nature of primary packaging elements:
- Polypropylene bottle
- Nitrile elastomer closure
- Aluminium cap

Sales presentations:
- 150-ml (500-dose) bottle.
- 150-ml (500-dose) bottle, box of 10 bottles.
- 300-ml (1 000-dose) bottle.
- 300-ml (1 000-dose) bottle, box of 10 bottles.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned .

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/052/001

8. DATE OF FIRST AUTHORISATION

25 November 2005

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

08 December 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).