SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIMUNE 407 ND+IB+EDS+ART emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.3-ml dose of vaccine 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 egg drop syndrome virus (EDS76), V127 strain, at least .....180 HI.U
Inactivated turkey rhinotracheitis virus, 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(s):
Paraffin oil .....170 to 186 mg

Excipient(s):

Thiomersal .....30 µg
Formaldehyde, at most .....90 µg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Whitish homogeneous emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (breeder and layer pullets).

4.2 Indications for use, specifying the 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 Mass41 strain,
- Avian pneumovirus in order to reduce respiratory signs linked to avian pneumovirus infection (swollen head syndrome).

Active immunisation of breeder and layer pullets in order to reduce egg drop linked to infection with egg drop syndrome virus (EDS76) without priming.

Newcastle disease, infectious bronchitis and egg drop syndrome 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.

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

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 veterinary medicinal 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 veterinary medicinal 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

Other precautions
Not applicable

4.6 Adverse reactions (frequency and seriousness)

Chickens:

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

[1] At the injection site. Lesions linked to the oily adjuvant were histologically observed in 87% of cases three weeks after injection, 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.

4.7 Use during pregnancy, lactation or lay

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

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 made on a case by case basis.

4.9 Amount(s) to be administered and administration route

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.

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

In addition to the adverse events mentioned in paragraph “Adverse events”, transitory apathy and slight oedema at injection site may occur after the administration of a double dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated vaccine in oily adjuvant against Newcastle disease, infectious bronchitis, egg drop syndrome (EDS76) and swollen head syndrome.
ATCvet code: ATC vet code: QI01AA18
The vaccine stimulates active immunity of breeder and layer pullets against egg drop syndrome (EDS76) (without priming), Newcastle disease, infectious bronchitis and swollen head syndrome, subsequent to priming with live vaccines against these diseases.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Paraffin oil
- Thiomersal.
- Formaldehyde.
- Ester of fatty acids and ethoxylated polyols.
- Ester of fatty acids and polyols.
- Water for injections.

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: 18 months.
Shelf-life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

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

6.5 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.

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

Medicines should not be disposed of via wastewater.

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

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 08327/5025

9. DATE OF FIRST AUTHORISATION

15 October 2004

10. DATE OF REVISION OF THE TEXT

January 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Approved: 18 June 2024

Gavin Hall