ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

500 doses, Bottle of 150 ml
10 x 500 doses, 10 Bottles of 150 ml
1 000 doses, Bottle of 300 ml
10 x 1 000 doses, 10 Bottles of 300 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIMUNE 303 ND+IB+ART emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.3 ml dose contains:
Inactivated Newcastle disease virus, Ulster 2C strain.....≥ 50 PD_{50}
Inactivated infectious bronchitis virus, Mass41 strain.....≥ 18 HI.U
Inactivated turkey rhinotracheitis virus (swollen head syndrome), VCO3 strain ..≥ 0.76 ODD

3. PACKAGE SIZE

0.3 ml/d
500 doses (150 ml)
10 x 500 doses (10 x 150 ml)
1 000 doses (300 ml)
10 x 1 000 doses (10 x 300 ml)

4. TARGET SPECIES

Chickens (breeder and layer pullets).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramuscular use.
Shake well before use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 08327/3020

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

500 doses, 150 ml
1 000 doses, 300 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIMUNE 303 ND+IB+ART emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose:
Inactivated:
- Newcastle disease virus, Ulster 2C strain .....≥ 50 PD_{50},
- Infectious bronchitis virus, Mass41 strain.....≥ 18 HI.U,
- Turkey rhinotracheitis virus, VCO3 strain .....≥ 0.76 ODD

0.3 ml/d
500 doses, 150 ml
1 000 doses, 300 ml

3. TARGET SPECIES

Chickens (breeder and layer pullets)

4. ROUTES OF ADMINISTRATION

For intramuscular use.
Shake well before use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened, use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

GALLIMUNE 303 ND+IB+ART emulsion for injection

2. Composition

Each 0.3 ml dose contains:
Inactivated Newcastle disease virus, Ulster 2C strain .....≥ 50 PD_{50}[1]
Inactivated infectious bronchitis virus, Mass41 strain.....≥ 18 HI.U
Inactivated turkey rhinotracheitis virus[2], VCO3 strain.....≥ 0.76 ODD
Thiomersal .....30 µg
Formaldehyde .....≤ 45 µg
Paraffin oil (as adjuvant) .....170 to 186 mg

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.

Whitish homogeneous emulsion.

3. Target species

Chickens (breeder and layer pullets).

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.

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.

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

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.

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

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must consult the relevant Member State's Competent Authority on the current vaccination policies as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

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).

9. Advice on correct administration

- 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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after “Exp.”.
Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 08327/3020

Pack sizes:
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.

15. Date on which the package leaflet was last revised

December 2023

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Marketing authorisation holder:
Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

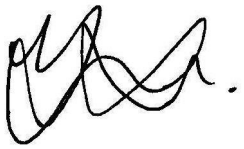
Manufacturer responsible for the batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Local representatives and contact details to report suspected adverse reactions:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

17. Other information

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



Approved: 12 April 2024