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
1000 doses, Bottle of 300 ml
10 X 1000 doses, 10 Bottles of 300 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1d (0.3ml):
Inactivated Newcastle Disease virus, Ulster 2C strain .....≥ $50PD_{50}$
Inactivated Infectious Bronchitis virus, Mass41 strain .....≥ 18 HI.U
Inactivated Egg Drop Syndrome virus (EDS76), V127 strain .....≥ 180 HI.U
Inactivated Avian Rhinotracheitis virus (Swollen Head Syndrome), VCO3 strain ≥ 0.76 ODD
(culture substrate: hen eggs, Vero cells, duck embryo cells)*
*for Germany only

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

500 doses: 150ml
10 x 500 doses: 10 x 150ml
1,000 doses: 300ml
10 x 1,000 doses: 10 x 300ml

5. TARGET SPECIES

Chickens (breeder and layer pullets).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular route.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once opened, use immediately

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4217

VPA 10454/053/001

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

500 doses, 150 ml
1000 doses, 300 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1d (0.3ml):
- Inactivated:
  - Newcastle Disease virus, Ulster 2C strain .....≥ $50PD_{50}$,
  - Infectious Bronchitis virus, Mass41 strain.....≥ 18 HI.U,
  - Egg Drop Syndrome virus (EDS76), V127 strain.....≥ 180 HI.U,
  - Avian Rhinotracheitis virus, VCO3 strain .....≥ 0.76 ODD

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

500 doses, 150 ml
1,000 doses, 300 ml

5. TARGET SPECIES

Chickens (breeder and layer pullets)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Once opened, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4217

VPA 10454/053/001

17. MANUFACTURER'S BATCH NUMBER

Lot

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 0.3-ml dose contains:
Inactivated Newcastle Disease virus, Ulster 2C strain.....≥ $50PD_{50}$[1]
Inactivated Infectious Bronchitis virus, Mass41 strain .....≥ 18 HI.U
Inactivated Egg Drop Syndrome virus (EDS76), V127 strain .....≥ 180 HI.U
Inactivated Avian Rhinotracheitis virus (Swollen Head Syndrome), VCO3 strain≥ 0.76 ODD
(culture substrate: hen eggs, Vero cells, duck embryo cells)*
Thiomersal .....≤ 30 µg
Formaldehyde .....≤ 90 µg
Paraffin oil (as adjuvant) .....170 to 186 mg

*: for Germany only
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.
Whitish homogeneous emulsion for injection

4. INDICATION(S)

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 (Avian Rhinotracheitis).

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.

Avian Rhinotracheitis component:
- onset of immunity: 14 weeks after vaccination.
- duration of immunity: one laying period.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

No palpable reactions were observed following the injection of one dose of vaccine.
Lesions linked to the oily adjuvant were histologically observed very commonly (in 87% of cases) three weeks after injection in clinical studies (e.g. small quantities of oily residues and occasional aseptic micro-abscesses).
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 inform your veterinary surgeon.
Alternatively you can report via your national reporting system.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Chickens (breeder and layer pullets).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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), 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 PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated.
Protect from light.
Do not freeze.
Use immediately after opening.

12. SPECIAL WARNING(S)

Special warning for each target species: Vaccinate healthy animals only.

Special precautions for use in animals: Not applicable.

- 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.

Do not use in birds in lay and within 4 weeks before the start of the laying period.
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. Incompatibilities:Do not mix with any other vaccine/immunological product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2020

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.

Inactivated vaccine in oily adjuvant against Newcastle Disease, Infectious Bronchitis, Egg Drop Syndrome (EDS76) and Avian Rhinotracheitis.

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.

Approved 27 May 2020