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 302 ND+IB+EDS*
* for all countries except Austria, Belgium, Denmark and Sweden.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.3-ml dose contains:
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
(culture substrate: hen eggs, duck embryo cells)*
Thiomersal .....≤ 30 µg
Formaldehyde .....≤ 43.2 µg
Paraffin oil (as adjuvant) .....170 to 186 mg
(culture substrate: hen eggs, duck embryo cells)*: for Germany only

3. PHARMACEUTICAL FORM

Water-in oil emulsion for injection

4. PACKAGE SIZE

0.3 ml/d
500 doses. Bottle: 150ml
10 X 500 doses. 10 bottles of 150ml
1 000 doses. Bottle: 300ml
10 X 1 000 doses. 10 bottles of 300ml

5. TARGET SPECIES

Chickens (breeder and layer pullets).

6. INDICATION(S)

Active immunisation of breeder and layer pullets against Newcastle Disease, Infectious Bronchitis and Egg Drop Syndrome.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – see package leaflet before use.

10. EXPIRY DATE

EXP:
Use immediately after opening.

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2°C and +8°C, protected from light.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

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"

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 08327/4215

VPA 10454/051/001

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

500 doses, 150 ml
1000 doses, 300 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIMUNE 302 ND+IB+EDS*
* for all countries except Austria, Belgium, Denmark and Sweden.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose:
- 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,
- Paraffin oil

3. PHARMACEUTICAL FORM

Water-in oil emulsion for injection

4. PACKAGE SIZE

0.3 ml/d
500 doses, 150 ml
1000 doses, 300 ml

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

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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 08327/4215

VPA10454/051/001

17. MANUFACTURER'S BATCH NUMBER

Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET
GALLIMUNE 302 ND+IB+EDS

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 302 ND+IB+EDS*
* for all countries except Austria, Belgium, Denmark and Sweden.

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

Each 0.3-ml dose contains:
Inactivated Newcastle Disease virus, Ulster 2C strain .....≥ $50PD_{50}$
Inactivated Infectious Bronchitis virus, Mass41 strain .....≥ 18 HI.U
Inactivated Egg Drop Syndrome virus (EDS76), V127 strain .....≥ 180 HI.U
(culture substrate: hen eggs, duck embryo cells)*
Thiomersal .....≤ 30 µg
Formaldehyde .....≤ 43.2 µg
Paraffin oil (as adjuvant) .....170 to 186 mg
(culture substrate: hen eggs, duck embryo cells)*: 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
(1): Minimum protective dose according to monograph 0870 of Ph. Eur.

4. INDICATION(S)

Booster immunisation of breeder and layer pullets after vaccination with live vaccines against:
- Newcastle Disease virus
- Infectious Bronchitis virus

Active immunisation of breeder and layer pullets in order to reduce egg drop linked to infection with Egg Drop Syndrome virus EDS76 without priming.

- onset of immunity: 4 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.
In clinical studies, lesions linked to the oily adjuvant were observed histologically three weeks after injection in 87% of cases, e.g. small quantities of oily residues and occasional aseptic micro-abscesses.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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) and Infectious Bronchitis (strain Mass H120).

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

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport between +2°C and +8°C, protected from light. Do not freeze.
Use immediately after opening.

12. SPECIAL WARNING(S)

- Vaccinate only healthy 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 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 insert 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.
- Not to be used within 2 weeks before the onset of the laying and during 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.
- In addition to the adverse effects mentioned in paragraph «Adverse reactions», transitory apathy and slight oedema at injection site may occur after the administration of a double dose of vaccine.
- Do not mix with any other vaccine/immunological product.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2020

15. OTHER INFORMATION>

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

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