

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 1 blister (10 tablets x 1000 doses)
Box containing 10 blisters (100 tablets x 1000 doses)
Box containing 1 blister (10 tablets x 2000 doses)
Box containing 10 blisters (100 tablets x 2000 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IB88 NEO effervescent tablet for suspension for nebulisation for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose contains at least 4.0 log₁₀ EID₅₀ attenuated Infectious Bronchitis coronavirus, strain CR88121 (793B).

3. PHARMACEUTICAL FORM

Effervescent tablet for suspension for nebulisation.

4. PACKAGE SIZE

10 tablets of 1000 doses.
100 tablets of 1000 doses.
10 tablets of 2000 doses.
100 tablets of 2000 doses.
Each tablet provides 1000 doses.
Each tablet provides 2000 doses.

5. TARGET SPECIES

Broiler chickens

6. INDICATION(S)

Live attenuated vaccine against Infectious Bronchitis, strain CR88 (793B) in broiler chickens from 1 day of age.

Reduces clinical signs and lesions of respiratory disease caused by the coronavirus variant, strain CR88 (793B). Immunity has been demonstrated 21 days after vaccination. Duration of immunity: 6 weeks after vaccination.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

One dose of vaccine to be administered by nebulisation from 1 day old.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Wear respiratory and eye protection conforming to current European Standards.

Wash and disinfect hands after use.

10. EXPIRY DATE

EXP {month/year}

After reconstitution: use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze.

Do not keep unused tablets after removal from the blister.

Keep the blister(s) in the outer carton.

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

Dispose of waste material in accordance with local requirements.

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 SIGHT AND REACH 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

Manufactured using technology under license from Phibro Animal Health Corporation USA and its affiliates.

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4265

VPA 10454/056/001

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium blister containing 10 tablets of 1000 doses
Aluminium blister containing 10 tablets of 2000doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IB88 NEO
Effervescent tablet for suspension for nebulisation.
Chickens
1000 doses
2000 doses

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

GALLIVAC IB88 NEO, effervescent tablet for suspension for nebulisation for chickens

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 responsible for batch release:

Boehringer Ingelheim Animal Health France SCS, Laboratoire Porte des Alpes, Rue de l'Aviation, F-69800 Saint Priest - France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IB88 NEO effervescent tablet for suspension for nebulisation for chickens
Light beige, mottled, round tablets.

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

Each dose of vaccine contains:

- Attenuated Infectious Bronchitis coronavirus, strain CR88121 (793B), at least4.0 log₁₀ EID₅₀
- Excipientq.s. 1 dose

4. INDICATION(S)

Reduces clinical signs and lesions of respiratory disease caused by the coronavirus variant, strain CR88 (793B) in broiler chickens.

Immunity has been demonstrated 21 days after vaccination.

Duration of immunity: 6 weeks after vaccination.

5. CONTRAINDICATIONS

In the absence of trial data, future layers or breeders and chickens in lay must not be vaccinated.

6. ADVERSE REACTIONS

Vaccination may induce mild and very common respiratory signs, which may persist for up to 23 days, and commonly frothy lacrimation.

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).
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Broiler chickens from 1 day of age.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

One dose of vaccine to be administered by nebulisation from 1 day old.

9. ADVICE ON CORRECT ADMINISTRATION

- Use clean equipment free from any antiseptic and/or disinfectant for the preparation and administration of the vaccine.
- Use demineralised or distilled water for the preparation and administration of the vaccine. Dissolve the tablets in a volume of demineralised or distilled water appropriate for the type of spraying equipment to be used, and the number of doses to be administered.
- Wait until complete dissolution of the tablet(s) before using the vaccine solution.
- Spray equipment should be used which is capable of producing droplets of average diameter 80 to 150 µm. Do not use "fogger"-type sprayer or equipment producing droplets of less than 50 microns for the administration of the vaccine.
- The vaccine should be sprayed as evenly as possible over the birds to ensure that each bird receives a full dose (for further information on sprayer equipment, contact the manufacturer).
- The ventilation system of the poultry house should be inoperative during the spray administration.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2°C - 8°C). Do not freeze.
Keep the blister(s) in the outer carton.
Do not keep unused tablets after removal from the blister.
Do not use after the expiry date which is stated on the blister.
Shelf-life for reconstituted vaccine: 2 hours.
Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special warnings for each target species:

GALLIVAC IB88 NEO vaccination does not replace the vaccination schedule against classical Infectious Bronchitis.

Special precautions for use in animals:

Only healthy birds should be vaccinated.

The vaccinal virus can spread to non-vaccinated birds, but no trend towards reversion to virulence was demonstrated in laboratory trials.

Nevertheless, care should be taken to prevent spread of vaccine virus to susceptible birds such as replacement layers and young birds.

It is recommended to vaccinate all chickens on a site at the same time.

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

Care should be taken during dissolution and administration of the vaccine. During preparation of the vaccine suspension and administration by coarse spray, the operator should wear respiratory and eye protection conforming to current European standards. For further information contact the manufacturer.

Hands should be washed and disinfected after vaccinating.

Lay:

Do not use in future layers, or breeders and chickens in lay.

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 (symptoms, emergency procedures, antidotes):

Administration of ten doses of vaccine may induce mild upper respiratory signs that may persist for up to 17 days and/ or a transient reduced weight gain.

Incompatibilities:

Do not mix with any other medicinal product.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

1000-dose tablets packaged in aluminium blister (10 tablets per blister), presented in a box of 1 or 10 blisters.

2000-dose tablets packaged in aluminium blister (10 tablets per blister), presented in a box of 1 or 10 blisters.

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

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A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line that curves downwards to the right.

Approved 24 September 2020