

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (10x2000 doses and  
10x1000 doses CARTON)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Gallivac IB88

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Live attenuated vaccine against Infectious Bronchitis, strain CR88 (793B) in broiler chickens from 14 days of age

**3. PHARMACEUTICAL FORM**

Powder for nebuliser suspension

**4. PACKAGE SIZE**

10 x 1000 dose vials  
10 x 2000 dose vials

**5. TARGET SPECIES**

Broiler Chickens

**6. INDICATION(S)**

Reduces clinical signs and lesions of respiratory disease caused by the coronavirus variant, strain CR88 (793B). Immunity has been demonstrated 17 days after vaccination, and duration of immunity is at least 5 weeks.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Each dose of reconstituted vaccine contains at least 4.0 log<sub>10</sub> EID<sub>50</sub> attenuated Infectious Bronchitis coronavirus, strain CR88121 (793B). Each vial contains 1000 doses. One dose of vaccine to be administered by nebulisation at 14 days of age.

**8. WITHDRAWAL PERIOD**

Zero days

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet for user instructions, warnings and disposal advice.  
Wear respiratory and eye protection conforming to current European Standards.  
Wash and disinfect hands after use.

**10. EXPIRY DATE**

## **11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator. Protect from light. Do not freeze.

In use shelf life: 2 hours. Keep the container in the outer carton.

## **12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of 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

POM-V

To be supplied only on veterinary prescription.

## **14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH 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

## **16. MARKETING AUTHORISATION NUMBER**

Vm 08327/4159

## **17. MANUFACTURER’S BATCH NUMBER**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (1000 doses  
and 2000 doses VIAL LABELS)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Gallivac IB88

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Live attenuated vaccine against Infectious Bronchitis, strain CR88 (793B) in broiler chickens from 14 days of age

**3. PHARMACEUTICAL FORM**

Powder for nebuliser suspension

**4. PACKAGE SIZE**

1000 doses

2000 doses

**5. TARGET SPECIES**

Broiler Chickens

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Each dose of reconstituted vaccine contains at least  $4.0 \log_{10} \text{EID}_{50}$  of attenuated infectious bronchitis coronavirus CR88121 (793B).

Read the package leaflet for user instructions, warnings and disposal advice.

**8. WITHDRAWAL PERIOD**

Zero days

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet for user instructions, warnings and disposal advice.

**10. EXPIRY DATE**

Expiry:

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator. Protect from light. Do not freeze. Shelf life for reconstituted vaccine: 2 hours.

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

Read the package leaflet for user instructions, warnings and disposal advice.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

For animal treatment only

POM-V

**14. THE WORDS “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

**16. MARKETING AUTHORISATION NUMBER**

Vm 08327/4159

**17. MANUFACTURER’S BATCH NUMBER**

Batch No:

**PACKAGE LEAFLET FOR: Gallivac IB88**

**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

Manufacturer for the batch release

**Merial** - Laboratoire Porte des Alpes  
Rue de l'Aviation 69800 Saint Priest - France.

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Gallivac IB88  
Powder for nebuliser suspension.

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

Each dose of reconstituted vaccine contains:

- Attenuated Infectious Bronchitis coronavirus,  
strain CR88121 (793B), at least .....4.0 log<sub>10</sub> EID<sub>50</sub>
- Excipient .....q.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 17 days after vaccination, and the duration of immunity is at least 5 weeks.

**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 transient upper respiratory signs that may persist for up to 14 days.

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 14 days of age.

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

One dose of vaccine to be administered by nebulisation at 14 days of age.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Apply usual aseptic procedures.

- 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 reconstitution and preparation of the vaccine. Reconstitute the freeze-dried pellet in demineralised or distilled water (3 to 5 ml) then dilute it in a volume appropriate for the type of spraying equipment to be used, and the number of doses to be administered.
- 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.
- Care should be taken during reconstitution and administration of the vaccine. 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.

## **10. WITHDRAWAL PERIOD(S)**

Zero days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Store between +2°C and +8°C, protected from light. Do not freeze.

Keep the container in the outer carton.

Do not use after the expiry date which is stated on the label.

Shelf-life for reconstituted vaccine: 2 hours.

Keep out of the reach and sight of children.

## **12. SPECIAL WARNING(S)**

Only healthy birds should be vaccinated.

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

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.

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

Do not mix with any other medicinal product.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Month YYYY

### **15. OTHER INFORMATION**

UK	POM-V	Vm 08327/4159
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1,000-dose glass bottle, with butyl elastomer closure, box of 1 and 10 bottles.

2,000-dose glass bottle, with butyl elastomer closure, box of 1 and 10 bottles.

2,500-dose glass bottle, with butyl elastomer closure, box of 1 and 10 bottles.

5,000-dose glass bottle, with butyl elastomer closure, box of 1 and 10 bottles.

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

Approved: 29 November 2018

