SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IB88

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:
Attenuated Infectious Bronchitis coronavirus, strain CR88121 (793B), at least 4.0 $\log_{10}$ EID_{50}
Excipient …… q.s. 1 dose

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for nebuliser suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Broiler chickens from 14 days of age.

4.2 Indications for use, specifying the target species

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.

4.3 Contra-indications

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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

i. 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.

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

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.

4.6 Adverse reactions (frequency and seriousness)

Vaccination may induce mild and transient upper respiratory signs that may persist for up to 14 days.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal Period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Immunologicals for aves, domestic fowl, live viral vaccines

ATCVet code: QI01AD07

The vaccine contains the live attenuated CR88121 strain of Infectious Bronchitis, belonging to the CR88 (793B) group of the variant coronaviruses. After administration, the vaccine stimulates active immunity against the variant coronaviruses of group CR88 (793B).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Freeze-drying substrate.

6.2 Major incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

Shelf-life of vaccine as packaged for sale: 15 months.
Shelf-life for reconstituted vaccine: 2 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

1,000-dose (type I glass, 10 ml) bottle, with butyl elastomer closure, box of 1 and 10 bottles
2,000-dose (type I glass, 10 ml) bottle, with butyl elastomer closure, box of 1 and 10 bottles
2,500-dose (type I glass, 10 ml) bottle, with butyl elastomer closure, box of 1 and 10 bottles
5,000-dose (type I glass, 10 ml) bottle, with butyl elastomer closure, box of 1 and 10 bottles

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBERS

Vm 08327/4159

9. DATE OF FIRST AUTHORISATION

19 February 1999

10. DATE OF REVISION OF THE TEXT

November 2018

Approved: 29 November 2018