# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IB88 NEO effervescent tablet for suspension for nebulisation for chickens

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose 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

Effervescent tablet for suspension for nebulisation.
Light beige, mottled, round tablets.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Broiler chickens from 1 day 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 21 days after vaccination.
Duration of immunity: 6 weeks after vaccination.

### 4.3 Contraindications

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

### 4.5 Special precautions for use

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 the 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.

**4.6 Adverse reactions (frequency and seriousness)**

Mild respiratory signs have been reported very commonly in studies and signs may persist for up to 23 days.
Frothy lacrimation has been reported commonly in studies.

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).

**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 interactions**

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.

**4.9 Amounts to be administered and administration route**

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

**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 PHARMACOLOGICAL or 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

Casein hydrolysate
D-mannitol
Sodium hydroxide
Water for injections
Sodium hydrogen carbonate
Citric acid (anhydrous)
Magnesium stearate

### 6.2 Major incompatibilities

Do not mix with any other medicinal product.

### 6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf-life for reconstituted vaccine: 2 hours.

### 6.4 Special precautions for storage

Store and transport between +2°C and +8°C. Do not freeze.
Do not keep unused tablets after removal from the blister.

### 6.5 Nature and composition of immediate packaging

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.
Not all pack sizes may be marketed.

### 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

## 7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/056/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 February 2016
Date of last renewal: 11 December 2020

## 10 DATE OF REVISION OF THE TEXT

December 2020