## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IBD S706 NEO Effervescent tablet for use in drinking water for chickens.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of vaccine contains:

**Active substance:**
Infectious Bursal Disease virus, attenuated strain S706, $10^{4.0}$ to $10^{5.3}$ CCID50*
* CCID50: Cell Culture Infective Dose 50%

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Saccharose |
| Lactalbumin hydrolysate |
| Sodium glutamate |
| Water for injections |
| Anhydrous citric acid |
| Sodium bicarbonate |
| Magnesium stearate |
| Sunset Yellow FCF (E 110) |
| Purified water |

Beige to pale orange, round tablet.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Chickens (broilers, future layers and broiler breeders).

### 3.2 Indications for use for each target species

Active immunisation of chickens to protect against mortality and to reduce lesions associated with Infectious Bursal (Gumboro) Disease.
Onset of immunity: 2 weeks after the first administration.
Duration of immunity: immunity has been shown under field conditions to persist throughout the rearing period.

### 3.3 Contraindications

None.

### 3.4 Special warnings

Vaccinate healthy animals only.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Due to the spread of the vaccine virus, it is recommended to separate vaccinated and unvaccinated birds.

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

Care should be taken during dissolution of the vaccine and drinking water application.
Hands should be washed and disinfected after vaccinating.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Chickens (broilers, future layers and broiler breeders):

| | |
|---|---|
| Undetermined frequency (cannot be estimated from the available data): | Bursal disorder[1] |

[1] When vaccine virus is passed from bird to bird damage to the bursa is increased. However, this is not considered to result in an immunosuppressive effect.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

### 3.8 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.

### 3.9 Administration routes and dosage

In drinking water use.

The vaccination schedule is:
Two doses:
. At 8-12 days of age, one dose administered to each bird via the drinking water.
. At 17-25 days of age, one dose administered to each bird via the drinking water.
However, the choice of vaccination schedule may be adapted by the prescribing veterinary surgeon taking into account the historical vaccination program employed, level of IBD field challenge on the farm and level of maternally derived antibody in the birds to be vaccinated (high levels of maternally derived antibodies can interfere with an active immune response to vaccination).

Reconstitution should be in plastic, not metal containers. Only sterile antiseptic-free materials should be used for the preparation of vaccine solution.
The tablet vaccine must not be dissolved in water containing antiseptic or disinfectant.

The vaccine should be dissolved in the drinking water immediately before use.
Wait until complete dissolution of the tablets before using the vaccine suspension. The reconstituted vaccine is a light yellow solution, and a thin foam layer may form over the surface.
The vaccine should be administered to the birds in the drinking water over a 1-2 hour period.
The volume of water required should be calculated according to the water consumption recorded a day or so before vaccination during a 2 hour period at the same period of the day as the scheduled vaccination, and treated with skimmed milk powder at a rate of 2 g per litre or 10 g per gallon at least 20 minutes prior to reconstituting the vaccine.
The required number of doses should be reconstituted in a small volume of water which has been treated with the milk powder in a clean, disinfectant-free plastic bucket.
Once reconstituted, add the vaccine to the drinking water volume previously calculated and mix thoroughly.
Drinker lines should be primed with vaccinated water prior to allowing the birds access to the drinkers.
Birds may be deprived of water for up to one and a half hours prior to vaccination, if necessary, in order to encourage drinking. Activating feeding systems during vaccination will also encourage drinking.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions other than those described under section 3.6 were observed following the administration of an overdose.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

### 3.12 Withdrawal periods

Zero days.

## 4. IMMUNOLOGICAL INFORMATION

### 4.1 ATCvet code :

QI01AD09
To stimulate active immunity against avian infectious bursal disease virus (Gumboro disease) infection.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after opening the blister: use immediately.

Shelf life after reconstitution according to directions: 2 hours.

### 5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not keep unused tablets removed from the blister.
Keep the blisters in the outer carton.

### 5.4 Nature and composition of immediate packaging

Nature of primary packaging:
Polyamide - aluminium – PVC / aluminium blister.

Nature of outer packaging:
Cardboard box.

Box of 1 blister of 10 tablets of 2,000 doses.
Box of 1 blister of 10 tablets of 5,000 doses.
Box of 10 blisters of 10 tablets of 2,000 doses.
Box of 10 blisters of 10 tablets of 5,000 doses.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH.

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/079/001

## 8. DATE OF FIRST AUTHORISATION

08/01/2021

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

21/09/2026

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).