# Summary of Product Characteristics

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

Excipients:
Excipient qs 1 dose

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Effervescent tablet for suspension
Beige to pale orange, round tablet

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Chickens (broilers, future layers and broiler breeders).

### 4.2 Indications for use, specifying the 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.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

Vaccinate healthy animals only

### 4.5 Special precautions for use

Special precautions for use in animals

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 resuspension of the vaccine and drinking water application. Hands should be washed and disinfected after vaccinating.

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

Laboratory studies have shown that when the vaccine virus was experimentally passed from bird to bird, damage to the bursa increased. This was detected by histological examination of the bursae. However, this is not considered to result in an immunosuppressive effect.

**4.7 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.

**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**

The suggested 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).

Method of administration: For use in drinking water.
Reconstitution should be in plastic, not metal containers. Only sterile antiseptic-free materials should be used for the preparation of vaccine suspension.
The tablet vaccine must not be resuspended in water containing antiseptic or disinfectant.
The vaccine should be resuspended in the drinking water immediately before use.
Wait until complete resuspension of the tablets before using the vaccine suspension. The reconstituted vaccine is a light yellow suspension, 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 2g per litre or 10g 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.

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

No adverse reactions other than those described under section 4.6 were observed following the administration of an overdose.

**4.11 Withdrawal period(s)**

Zero days

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for aves, live viral vaccines for domestic fowl.
ATC vet code: QI01AD09
To stimulate active immunity against avian infectious bursal disease virus (Gumboro disease) infection.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Saccharose
Lactalbumin hydrolysate
Sodium glutamate
Water for injections
Anhydrous citric acid
Sodium bicarbonate
Magnesium stearate
Sunset Yellow FCF (E 110)
Purified water

### 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: 2 years
Shelf life after opening the blister: use immediately
Shelf life after reconstitution according to directions: 2 hours.

### 6.4 Special precautions for storage

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

### 6.5 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.

### 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 product 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)

VPA10454/079/001

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

Date of first authorisation: 08 January 2021

## 10 DATE OF REVISION OF THE TEXT