

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IBD INT, lyophilisate for oculonasal suspension/use in drinking water, for chickens

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains

### Active substance:

Attenuated live Infectious Bursal Disease virus,  
IM strain VMG 91

$10^{4.0}$  to  $10^{5.0}$  TCID<sub>50</sub>\*

\*TCID<sub>50</sub> = 50% tissue culture infective dose

### Excipients:

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension/use in drinking water  
Cream to reddish coloured lyophilisate

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Chickens.

### 4.2 Indications for use, specifying the target species

For active immunisation of chickens (broilers, future layers and breeders), with maternally derived antibodies, to prevent mortality and clinical disease, due to infection caused by Avian Infectious Bursal Disease viruses.

Onset of immunity: 2 weeks after vaccination

Duration of immunity: 4 weeks after vaccination

### 4.3 Contraindications

None.

#### **4.4 Special warnings for each target species**

Please refer to section 4.9.

Vaccinate healthy animals only.

#### **4.5 Special precautions for use**

##### Special precautions for use in animals

The vaccine strain can spread to susceptible, unvaccinated chickens for at least 10 days following vaccination. The vaccine virus has shown the potential to increase in virulence on bird to bird passage and may cause immunosuppression but does not induce clinical signs of disease. It is very important to take measures to ensure that the vaccine strain does not spread to unvaccinated chickens.

It is possible that the vaccine viruses can be spread to non-target susceptible species. Care should be taken to ensure that the vaccine virus does not spread to unvaccinated birds. Therefore, all birds in a flock should be vaccinated at the same time to reduce the risk of bird to bird transmission. Vaccinated birds should not be mixed with unvaccinated birds. Hygiene measures should be taken to prevent spread to other flocks. Vaccination of all chickens on the premises is recommended. Housing needs to be disinfected prior to restocking.

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

Wash and disinfect hands and equipment after vaccination.

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

In laboratory studies after administration of a 10-fold overdose, mild to moderate lymphocyte depletion in the bursa of Fabricius was observed very commonly 7 days after vaccine take (bursal lesion score 2.4). This depletion decreases and is followed by lymphocyte repopulation and complete regeneration of the bursa by day 28 post vaccination (bursal lesion score 0.2).

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 birds in lay or within 4 weeks before the onset 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

One dose of vaccine should be administered to each chicken in drinking water, or by the ocular route from 8 days of age depending on MDA level of the flock.

The optimal vaccination date is influenced by a number of factors, such as status of maternally derived antibodies, type of bird, infection pressure, housing and management conditions.

Maternally derived antibodies (MDA) can interfere with the immunity induced by live IBD vaccines, so the optimum age for vaccination depends on both the level of residual MDA against Avian IBD virus in the flock and the ability of the vaccine strain of Avian IBD virus to induce the required level of immunity in the presence of MDA. To predict the age when the MDA titre has sufficiently decreased to allow effective vaccination (break-through titre), testing of serum samples of at least 18 chicks by serology and application of the Deventer Formula is advised. A break-through titre of 125 should be used.

The Deventer formula is as follows:

$$\text{Vaccination age} = \{ (\log_2 \text{ titre bird\%} - \log_2 \text{ breakthrough}) \times t_{\frac{1}{2}} \} + \text{age at sampling} + \text{correction 0-4}$$

In which:

Bird% = ELISA titre of the bird representing a certain percentage of the flock

breakthrough = breakthrough (ELISA) titre of the vaccine to be used

$t_{\frac{1}{2}}$  = half-life time (ELISA) of the antibodies in the type of chickens being sampled

Age sampling = age of the birds at sampling

Correction 0-4 = extra days when the sampling was done at 0 to 4 days of age.

A high homogeneity of MDA levels in the flock is important to define the correct timing of vaccination and guarantees a better active immune response to the vaccine. In case of a non-homogenous flock where antibody levels vary widely between birds (i.e. CV greater than 30%), or the stock originates from different sources, it is recommended to repeat the vaccination. In such cases, timing of the first and second vaccination should be determined simultaneously, with two different percentages

(corresponding to the percentages of the flock that can be efficaciously vaccinated) of all serum samples collected on the sampling day, using the Deventer formula.

### *1. In drinking water use*

- Reconstitute the vaccine in a small amount of cool and clean water without traces of chlorine, other disinfectants or impurities, in a number of doses corresponding to the number of birds to be vaccinated. Where the number of birds is between the standard dosages, the next higher dosage should be used.
- Vaccine should be reconstituted immediately before use.
- Measure the correct volume of water for the number of birds to be vaccinated. The volume of water for dilution depends on the age of the birds, breed, housing conditions and weather conditions.
- The reconstituted vaccine should be diluted in the amount of water which will be consumed within 1.5 to 2.0 hours (taking into account the different types of drinking systems for poultry).
- In order to determine the quantity of water in which the vaccine will be diluted, measure the volume of water consumed within a two hours period one day before vaccination.
- As an orientation guide for younger chickens (until 3rd week of life), apply the reconstituted vaccine to cold and fresh water at the rate of 1,000 doses of vaccine to 1 litre of water per day of age for 1,000 chickens, e.g. 8 litres would be needed for 1,000, 8 day old chickens.
- In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to immunisation (birds drinking behaviour varies, depending on the air temperature, type of birds, breed, management, weather conditions).
- The drinking system should be clean, without traces of chlorine, other disinfectants or impurities.
- If needed, turn the lights down low when the water is turned off. After the vaccine is in the drinking system, increase light intensity again. Increased light intensity will stimulate the birds to look for food and water.
- Always make sure that there is food available when vaccinating. Birds will not drink if they have no food to eat.

### *2. Oculonasal use*

- Reconstitute 1000 doses of the vaccine in 100 ml distilled water.
- A dose of reconstituted vaccine is 0.1 ml, i.e. two drops, irrespective of poultry age, weight and type. Instill one drop into the eye and one drop into the nose opening.

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

After the administration of a 10-fold overdose, no adverse reactions other than those described in section 4.6 were observed.

#### **4.11 Withdrawal period(s)**

Zero days.

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group:

Live avian infectious bursal disease virus (Gumboro disease) vaccines for domestic fowl

ATCvet code: QI01AD09

To stimulate active immunity against Infectious Bursal Disease virus in chickens.

The vaccine strain is an intermediate strain with an average bursal lesion score of 0.2 at 28 days after administration of 10-times the maximum dose.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Povidone K 25  
Bacto peptone  
Monosodium glutamate  
Potassium dihydrogen phosphate  
Potassium hydroxide

#### **6.2 Major incompatibilities**

Do not mix with any other veterinary medicinal product.

#### **6.3 Shelf-life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after reconstitution according to directions: 3 hours.

#### **6.4 Special precautions for storage**

Store in a refrigerator (2 °C– 8 °C).

Protect from light.

Do not freeze.

### **6.5 Nature and composition of immediate packaging**

The vaccine is filled into 4 ml or 10 ml colourless glass vials (type I), which are closed with brombutyl rubber stoppers and sealed with aluminium caps.

Packaging sizes:

Carton box with 10 vials of 1000 doses of vaccine.

Carton box with 10 vials of 2500 doses of vaccine.

Carton box with 10 vials of 5000 doses of vaccine.

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**

GENERA Inc  
Svetonedeljska cesta 2  
Kalinovica  
Rakov Potok  
10436  
Croatia

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA10405/004/001

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

Date of first authorisation: 7<sup>th</sup> January 2019

## **10 DATE OF REVISION OF THE TEXT**