

# SUMMARY OF PRODUCT FEATURES

## 1. Name of the veterinary medicinal product

AVINEW NEO EFFERVESCENT TABLET FOR CHICKENS AND TURKEYS

## 2. Qualitative and quantitative composition

One dose contains:

Active substance(s):

Live Newcastle Disease Virus .....  $5.5 - 7.0 \log_{10} \text{DIO}_{50}^{(*)}$

VG/GA-AVINEW strain

Excipient(s):

Brilliant Blue FCF (E133)

(\*)  $\text{DIO}_{50}$  : Dose infecting 50% of eggs.

For the full list of excipients, see section "List of excipients".

## 3. Pharmaceutical form

Effervescent tablet.  
Round, blue speckled tablet.

## 4. Clinical information

### **4.1. Target species**

Chickens (broilers, future laying pullets and future breeders) and turkeys.

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

In broiler chickens from 1 day old:

- Active immunization against Newcastle disease to reduce mortality and clinical signs associated with the disease.

Onset of immunity: 14 days after the first vaccination.

Duration of immunity induced by the vaccination schedule described in the section "Dosage and route of administration": protection up to 6 weeks of age.

In future laying and breeding pullets from 4 weeks:

- Primary vaccination for active immunization against the drop in egg production due to Newcastle disease with a view to a booster with an inactivated vaccine (Ulster 2C strain) before the start of egg production.

For the duration of immunity of the complete vaccination schedule, see the package insert for the inactivated booster vaccine.

In turkeys from 1 day old:

- Active immunization against Newcastle disease to reduce mortality and clinical signs associated with the disease.

Onset of immunity: 21 days after the first vaccination.

Duration of immunity: 7 weeks after a single injection.

#### **4.3. Contraindications**

None.

#### **4.4. Specific warnings for each target species**

Vaccinate only healthy animals.

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

##### **i) Special precautions for use in animals**

Vaccine virus can spread to unvaccinated birds. In turkeys, the spread was found to be less than 21 days after administration of the overdose corresponding to 10 times the recommended dose. Infection of unvaccinated birds with vaccine virus from vaccinated birds does not produce any signs of pathology. On the other hand, the laboratory test for reversion to virulence showed that the vaccine virus does not show any tendency to acquire any pathogenic character after ten passages in chickens. Thus, viral spread to unvaccinated birds can, in the current state of knowledge, be considered as harmless.

In turkeys, the onset of immunity was assessed in seronegative EOPS birds. The impact of maternally derived antibodies on the immediate vaccine response in turkeys is unknown. The duration of immunity was studied in the presence of maternally derived antibodies.

#### **(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Handle the vaccine solution with care.

Newcastle disease virus can cause transient conjunctivitis in humans. Since this vaccine has been prepared with live and attenuated microorganisms, appropriate measures must be taken to avoid contamination of the handler and other persons involved in the vaccination. Therefore, it is recommended to wear protective eye and respiratory equipment, in accordance with current European standards, during the preparation and administration of the vaccine suspension. For further information, contact the manufacturer.

Wash and disinfect your hands after vaccination.

#### **iii) Other precautions**

None.

#### **4.6. Adverse reactions (frequency and severity)**

Not known.

In future laying and breeding hens, refer to the leaflet for the inactivated booster vaccine.

#### **4.7. Use during pregnancy, lactation or laying**

Do not use on birds during laying period.

#### **4.8. Drug interactions and other forms of interaction**

No information is available on the safety and efficacy of this vaccine when used with other veterinary medicinal products. Therefore, the decision to use the vaccine before or after another veterinary medicinal product must be made on a case-by-case basis.

#### **4.9. Dosage and route of administration**

##### In broiler chickens :

Primary vaccination by ocular route (drop in the eye) or oculo-nasal route (using a spray): from 1 day of age.

Oral booster (in drinking water): at 2-3 weeks of age.

It is recommended to keep a minimum period of 2 weeks between the two vaccinations.

##### In future laying and future breeding pullets :

Two administrations by ocular route (drop in the eye), by oculo-nasal route (using a sprayer) or by oral route (in drinking water): at the age of 4 and 8 weeks.

Vaccination with the drug should be followed by vaccination with an inactivated vaccine (Ulster 2C strain) before laying for sufficient efficacy.

#### In turkeys :

Vaccination by oculo-nasal route (using a sprayer): from 1 day of age.

#### Method of administration :

To reconstitute and prepare the vaccine, use clean, cold water.

Use clean equipment free of any trace of disinfectant and/or antiseptic for vaccine preparation and administration.

Wait until the tablet is completely dissolved before using the vaccine solution. The reconstituted vaccine has the appearance of a blue solution, and a thin film of foam may form on its surface.

- *Individual vaccination* : ocular route. For 1000 birds, dissolve one 1000-dose tablet in 50 mL of boiled and cooled drinking water without chlorine prepared in a clean container free of any trace of disinfectant and/or antiseptic. Wait for the tablet to completely dissolve, then transfer the vaccine solution into the dropper using a syringe. It is recommended to prepare the vaccine in a clean room away from animals.

Use a calibrated dropper to dispense 50 µL drops.

Place a drop of the vaccine solution on the eye of each bird, wait for the drop to spread and then release the bird.

- *Mass vaccination* : oral route. For 1000 birds, dissolve one 1000-dose tablet in a volume of chlorine-free drinking water intended to be absorbed in one or two hours.

If using tap water, add skimmed milk powder at a rate of 2.5 g per litre of water to neutralise traces of chlorine.

Distribute the vaccine solution to birds previously deprived of water for 2 hours.

- *Mass vaccination* : respiratory route. For 1000 birds, dissolve one 1000-dose tablet in a volume of chlorine-free drinking water to be adapted to the type of sprayer used (pressure sprayer or rotating cone sprayer).

Spray the vaccine solution above the birds using a sprayer capable of producing microdroplets (average diameter: 80-100 µm).

Ensure that the birds are sufficiently packed together when spraying to ensure good distribution of the vaccine. The poultry house ventilation system must not be running during spraying.

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

No adverse effects were observed after administration of 10 times the recommended dose of vaccine.

#### **4.11. Waiting time**

Zero days.

### **5. Immunological properties**

Pharmacotheapeutic group: Immunological products, avian vaccines, live viral vaccines, Newcastle disease virus.

ATC-vet code: QI01AD06.

The vaccine contains live Newcastle disease virus, strain VG/GA-AVINEW. This lentogenic strain is naturally apathogenic for chickens (genotype I, class II). Vaccination induces active immunization against Newcastle disease, demonstrated by virulent challenge, in broilers and turkeys.

### **6. Pharmaceutical information**

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

Brilliant Blue FCF (E 133)  
Casein hydrolysate  
Mannitol  
Povidone  
Sucrose  
Monopotassium  
phosphate Dipotassium phosphate  
Potassium glutamate  
Bovine albumin fraction V  
Purified water  
Anhydrous citric acid  
Sodium bicarbonate  
Magnesium stearate

#### **6.2. Major incompatibilities**

The presence of antiseptic and/or disinfectant in the water or material used to dissolve the tablet is incompatible with effective vaccination.

Do not mix with other veterinary medicinal products.

#### **6.3. Retention period**

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

Shelf life after reconstitution according to instructions: 2 hours.

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

Store and transport refrigerated (2°C to 8°C).  
Do not store unused tablets removed from the immediate packaging.  
Keep the immediate packaging in its original packaging.

#### **6.5. Nature and composition of primary packaging**

Polyamide blister - aluminum – PVC / aluminum

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

Empty packaging and any remaining product must be disposed of in accordance with current practices governed by waste regulations.

#### **7. Marketing authorisation holder**

BOEHRINGER INGELHEIM ANIMAL HEALTH FRANCE  
29 AVENUE TONY GARNIER  
69007 LYON  
FRANCE

#### **8. Marketing authorisation number(s)**

FR/V/3692068 8/2014

Box of 1 thermoformed blister pack of 10 tablets of 1000 doses  
Box of 1 thermoformed blister pack of 10 tablets of 2000 doses  
Box of 10 thermoformed blister packs of 10 tablets of 1000 doses  
Box of 10 thermoformed blister packs of 10 tablets of 2000 doses

Not all presentations may be marketed.

#### **9. Date of first authorization/renewal of authorization**

09/17/2014 - 09/17/2019

#### **10. Date of text update**

02/18/2022