SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AVINEW NEO effervescent tablet for chickens and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Live Newcastle disease virus, VG/GA-AVINEW strain 5.5 – 7.0 $\log_{10}$ EID_{50}(*)

(*) EID_{50}: Egg Infective Dose 50 per cent.

Excipients:
Brilliant blue FCF (E 133)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablet.
Blue mottled, round tablet.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (broiler, future layer and future breeder pullets).
Turkeys

4.2 Indications for use, specifying the target species

In broiler chickens from the age of one day:
- Active immunisation against Newcastle disease to reduce mortality and clinical signs associated with the disease.
Onset of immunity: 14 days after primary vaccination.
Duration of immunity induced by the vaccination scheme described under section 4.9: protection until the age of 6 weeks.

In future layer and future breeder pullets from the age of 4 weeks:
- Priming for active immunisation against egg drop caused by Newcastle disease before vaccination with an inactivated vaccine (strain Ulster 2C) prior to the beginning of lay.
For duration of immunity of full schedule, see the leaflet of the inactivated booster vaccine.

In turkeys from the age of one day:
- Active immunisation against Newcastle disease to reduce mortality and clinical signs associated with the disease.
Onset of immunity: 21 days after primary vaccination.
No data is available on the duration of immunity.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy birds only.

4.5 Special precautions for use

Special precautions for use in animals

Vaccine virus can spread to unvaccinated birds. In turkeys, this spread has been shown to be less than 21 days after administration of a 10-time overdose. Infection of unvaccinated birds with the vaccine virus from vaccinated birds does not induce any sign of disease. Moreover, a reversion to virulence trial carried out in the laboratory has shown that the vaccine virus does not acquire any pathogenic characteristic after 10 passages in chickens. Therefore, spread to unvaccinated birds, in the present state of knowledge, can be considered as safe.

In turkeys, the onset of immunity was evaluated in SPF seronegative birds. The impact of maternally derived antibodies on the response to vaccination in turkeys is unknown.

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

Care should be taken when handling the vaccine solution.
Newcastle disease virus can cause a transitory conjunctivitis in man. Since this vaccine has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process. Therefore, during preparation and administration of the vaccine suspension, it is recommended to wear respiratory and eye protection in compliance with current European standards. For more information, contact the manufacturer.
Hands should be washed and disinfected after vaccinating.

4.6 Adverse reactions (frequency and seriousness)

None known.
In future layer and future breeder pullets, refer to the leaflet of the inactivated booster vaccine.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay.

4.8 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.

4.9 Amounts to be administered and administration route

In broiler chickens:
Primary vaccination by ocular route (eye drop application) or oculonasal route (coarse spray application): from the age of one day.
Booster vaccination by oral route (drinking water application): at the age of 2 to 3 weeks.
The minimal interval between the two vaccinations should be of 2 weeks.

In future layer and future breeder pullets:
Two administrations by ocular route (eye drop application), oculonasal route (coarse spray application) or oral route (drinking water application): at the age of 4 weeks and 8 weeks.
Vaccination with the product should be followed by vaccination with an inactivated vaccine (strain Ulster 2C) prior to the beginning of lay to provide sufficient efficacy.

In turkeys:
Vaccination by oculonasal route (coarse spray application): from the age of one day.

Method of administration:
To reconstitute and prepare the vaccine, use clean cold water.
For the preparation and administration of the vaccine, use clean material free from disinfectant and/or antiseptic.
Wait until complete dissolution of the tablets before using the vaccine solution. The reconstituted vaccine is a blue solution, and a fine foam layer may form over the surface.

- Individual vaccination: ocular use

For 1,000 birds, dissolve a 1,000-doses tablet into 50 ml of boiled and cooled non chlorinated drinking water prepared in a clean container free from disinfectant and/or antiseptic. Wait until complete dissolution of the tablet, then use a syringe to transfer the vaccine solution to the dropper. It is recommended to prepare the vaccine in a clean area separate from the animals.
Use a calibrated dropper, so as to distribute 50 µl-drops.
Place one drop of the vaccine solution on the eye of each bird, allow the drop to spread and release the bird.

- Mass vaccination, oral route:

For 1,000 birds, dissolve a 1,000-doses tablet into the volume of non chlorinated drinking water to be consumed within one to two hours.
When using mains water, treat all water to come into contact with the vaccine with skimmed milk powder at a rate of 2.5 g per litre in order to neutralise traces of chlorine.
Distribute the vaccine solution to the birds. Birds should be deprived of water for two hours prior to vaccination.

- Mass vaccination, coarse spray application:

For 1,000 birds, dissolve a 1,000-doses tablet in the volume of non chlorinated drinking water appropriate for the type of sprayer used (pressure-sprayer or sprayer with rotary cone).
Spray the vaccine solution above the birds using a spray capable of producing micro-droplets (mean diameter 80-100 µm).
For proper vaccine distribution, make sure that birds are closely confined together during spraying. The ventilation system of the poultry house should be inoperative during the spray administration.

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

No side-effect has been observed following administration of 10 times the recommended dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Aves-Live viral vaccines- Newcastle disease virus
ATCvet code: QI01AD06.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brilliant blue FCF (E 133)
Casein hydrolysate
Mannitol
Polyvidone
Sucrose
Potassium dihydrogen phosphate
Dipotassium phosphate
Potassium glutamate
Bovine albumin fraction V
Purified water
Citric acid, anhydrous
Sodium hydrogen carbonate
Magnesium stearate

6.2 Major incompatibilities

The presence of disinfectant and/or antiseptic in water and material used for the dissolution of tablets is not compatible with an effective vaccination.
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: 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:
Carton box

Box of 1 blister of 10 tablets of 1,000 or 2,000 doses
Box of 10 blisters of 10 tablets of 1,000 or 2,000 doses

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4266

9. DATE OF FIRST AUTHORISATION

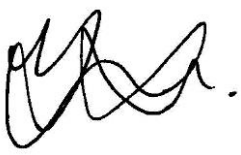
23 November 2015

10. DATE OF REVISION OF THE TEXT

September 2020

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.



Approved: 01 September 2020