SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avinew Neo effervescent tablet for suspension for chickens and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Newcastle disease virus, strain VG/GA-AVINEW, live 5.5 – 7.0 $\log_{10}$ EID_{50}[1]

[1] EID_{50}: Egg Infective Dose 50 per cent.

Excipients:

Qualitative composition of excipients and other constituents
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

Blue mottled, round tablet.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each 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 3.9: 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.
Duration of immunity: 7 weeks after a single administration.

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:

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-fold 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 immediate response to vaccination in turkeys is unknown. The duration of immunity was studied in the presence of maternally derived antibodies.

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

Care should be taken when handling the vaccine suspension.
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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens and turkeys:
None known.
In future layer and future breeder pullets, refer to the leaflet of the inactivated booster vaccine.
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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay.

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 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.

Instructions for reconstitution and 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 suspension.
The reconstituted vaccine is a blue suspension, 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 suspension 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 suspension 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 suspension 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 suspension 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.

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

No adverse event has been observed following administration of a 10-fold 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: QI01AD06.

The vaccine contains live Newcastle disease virus, strain VG/GA-AVINEW. The strain VG/GA-AVINEW 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 in turkeys.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

This veterinary medicinal product must not be administered using material and/or drinking water for dissolution containing disinfectant and/or antiseptic as the strain VG/GA-AVINEW may degrade in their presence.
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 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

Polyamide - aluminium – PVC / aluminium blister in a cardboard 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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 Animal Health UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08327/5043

8. DATE OF FIRST AUTHORISATION

23 November 2015

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

June 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 24 June 2026