

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box of 1 blister of 10 tablets of 1,000 doses
Box of 10 blisters of 10 tablets of 1,000 doses
Box of 1 blister of 10 tablets of 2,000 doses
Box of 10 blisters of 10 tablets of 2,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AVINEW NEO
Effervescent tablet for chickens and turkeys
Live Newcastle disease virus, VG/GA-AVINEW strain

2. STATEMENT OF ACTIVE SUBSTANCES

Live Newcastle disease virus, VG/GA-AVINEW strain 5.5 - 7.0 log₁₀ EID₅₀

3. PHARMACEUTICAL FORM

Effervescent tablet.

4. PACKAGE SIZE

1 blister of 10 tablets of 1000 doses. 10 x 1000 doses
10 blisters of 10 tablets of 1000 doses. 100 x 1000 doses
1 blister of 10 tablets of 2000 doses. 10 x 2000 doses
10 blisters of 10 tablets of 2000 doses. 100 x 2000 doses

5. TARGET SPECIES

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

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Chickens: Ocular, oculonasal or oral route.
Turkeys: oculonasal route
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted: use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufactured using technology under license from Phibro Animal Health Corporation USA and its affiliates.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4266

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

**MINIMUM PARTICULARS TO APPEAR ON
BLISTERS** Blister of 10 tablets of 1,000
doses Blister of 10 tablets of 2,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AVINEW NEO
Effervescent tablet for chickens and turkeys
1000 d.
2000 d.



2. NAME OF THE MARKETING AUTHORISATION HOLDER

BOEHRINGER
or



3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Lot: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

**PACKAGE LEAFLET FOR:
AVINEW NEO effervescent tablet for chickens and turkeys**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS, Laboratoire Porte des Alpes,
Rue de l'Aviation, F69800 Saint Priest - France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AVINEW NEO

Effervescent tablet for chickens and turkeys

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER
INGREDIENT(S)**

Each dose contains:

Active substance:

Live Newcastle disease virus, VG/GA-AVINEW strain 5.5 -7.0 log₁₀ EID₅₀ (*)

(*) EID₅₀: Egg Infective Dose 50 per cent.

Excipients:

Brilliant blue FCF (E 133)

Blue mottled, round tablet.

4. INDICATION(S)

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: 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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

In future layer and future breeder pullets, refer to the leaflet of the inactivated booster vaccine.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

Wait until complete dissolution of the tablets before using the vaccine solution. For the preparation and administration of the vaccine, use clean material free from disinfectant and/or antiseptic.

10. WITHDRAWAL

PERIOD(S) Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2°C-8°C).

Shelf life after reconstitution according to directions: 2 hours.

Do not keep unused tablets removed from the blister.

Keep the blisters in the outer carton.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy birds only

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 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 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.

Lay:

Do not use in birds in lay.

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.

Overdose (symptoms, emergency procedures, antidotes):

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

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

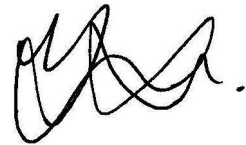
15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.

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 in turkeys.

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.

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A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 18 May 2022