

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AVINEW

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance:

Live Newcastle disease virus, VG/GA-AVINEW, at least 5.5 log₁₀ EID₅₀
EID₅₀: Egg Infective Dose 50 per cent.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for oral and ocular administration and for spraying.
Pale, homogeneous lyophilisate.

4. CLINICAL PARTICULARS

4.1 Target species

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

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 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 SPC of the inactivated booster vaccine.

4.3 Contraindications

None.

4.4 Special warnings

Vaccine virus can spread to unvaccinated birds. 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.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate healthy birds only.
Apply the usual aseptic procedures.

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

Care should be taken when handling the vaccine preparation.
Because Newcastle disease virus can cause a transitory conjunctivitis in man, 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 SPC of the inactivated booster vaccine.

4.7 Use during pregnancy, lactation or lay

Vaccination of chickens in lay is not recommended.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is, therefore, recommended that no other vaccines should be administered within 14 days before or after vaccination with Avinew.

4.9 Amounts to be administered and administration route

In broiler chickens:

Primary vaccination by ocular route (eye drop application) or oculo-nasal route (coarse spray application): from the age of one day.
Booster vaccinations 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), oculo-nasal 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.

Method of administration:

To reconstitute and prepare the vaccine, use clean cold water. For the preparation and administration of the vaccine, use sterile material free from disinfectant and/or antiseptic. Shake the reconstituted vaccine solution before use.

- Individual vaccination: ocular route

For 1,000 birds, reconstitute the lyophilisate pellet corresponding to 1,000 doses into 3 to 5 ml of boiled and cooled non chlorinated drinking water and subsequently dilute it into 50 ml of boiled and cooled non chlorinated drinking water.

Use 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, reconstitute the lyophilisate pellet corresponding to 1,000 doses into 3 to 5 ml of non chlorinated drinking water and subsequently dilute it 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 at the time of use to birds. Birds should be deprived of water for two hours prior to vaccination.

- Mass vaccination: respiratory route

For 1,000 birds, reconstitute the lyophilisate pellet corresponding to 1,000 doses into 3 to 5 ml of non chlorinated drinking water and subsequently dilute it into the volume of non chlorinated drinking water according to 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

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

ATCvet code: QI01AD06.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Protein hydrolysate
Mannitol
Polyvidone
Sucrose
Potassium glutamate
Potassium phosphate
Bovine albumin
Water

6.2 Incompatibilities

The presence of disinfectant and/or antiseptic in water and material used for the preparation of vaccine solution is not compatible with an effective vaccination.
Do not mix with other products.

6.3 Shelf life

16 months.
After reconstitution: 2 hours.

6.4 Special precautions for storage

Store between 2°C and 8°C, protected from light.

6.5 Nature and composition of immediate packaging

- Type-I glass bottle
- Butyl elastomer closure
- Aluminium cap

- Box of one 1,000-dose bottle
- Box of one 2,000-dose bottle
- Box of ten 1,000-dose bottles
- Box of ten 2,000-dose bottles

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

Disinfect empty bottles or bottles containing unused product before discarding.

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
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8. MARKETING AUTHORISATION NUMBER

Vm 08327/4207

9. DATE OF FIRST AUTHORISATION

23 July 2003

10. DATE OF REVISION OF THE TEXT

November 2018

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