

**SUMMARY OF PRODUCT CHARACTERISTICS
OF THE REFERENCE MEMBER STATE**

1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

AVINEW

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Live Newcastle disease virus, VG/GA strain, at least	5.5 log ₁₀ EID ₅₀
Excipient	q.s. 1 dose

3. PHARMACEUTICAL FORM

Freeze-dried vaccine to be diluted in appropriate diluent (non chlorinated drinking water).

4. IMMUNOLOGICAL PROPERTIES

The vaccine contains live Newcastle disease virus, VG/GA strain. The VG/GA strain is lentogenic and naturally apathogenic for chickens. The vaccine induces active immunisation against Newcastle disease, as demonstrated by challenge test.

5. CLINICAL PARTICULARS

5.0 Target species

Chickens.

5.1 Indications for use, specifying the target species

In chickens from the age of one day:

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

Duration of immunity induced by the vaccination scheme described under 5.7 : protection until the age of 6 weeks.

5.2 Contraindications and warnings in respect of other products used in the host, immunological status of host and physiological status of host

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other.

5.3 Undesirable effects in the target species (frequency and seriousness)

None known.

5.4 Special precautions for use

Vaccinate healthy birds only.

Apply the usual aseptic procedures.

5.5 Use during pregnancy and lactation

Vaccination of chickens in lay is not recommended.

5.6 Interaction with other vaccines and medicaments when administered in combination with the product

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.

5.7 Posology and method of administration

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.

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 non chlorinated drinking water and subsequently dilute it into 50 ml of 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.

5.8 Overdose (signs, emergency procedures, antidotes) (if necessary)

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

5.9 Special warnings for each target species

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.

5.10 Withdrawal periods

Zero days.

5.11 Special precautions to be taken by the person administering the 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.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities (major)

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.

6.2 Shelf-life

16 months.

After reconstitution: 2 hours.

6.3 Special precautions for storage

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

6.4 Nature and contents of container

- 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

6.5 Name or style and permanent address or registered place of business of the holder of the authorisation to place the product on the market

MERIAL
17, rue Bourgelat
69002 LYON
FRANCE

6.6 Special precautions for the disposal of unused product or waste material, if any

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. ADDITIONAL INFORMATION

Marketing Authorisation number:

Date of approval/last revision:

Condition of supply: subject to medical prescription

Authorised pack size: