LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AVINEW

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose:

Live Newcastle disease virus, VG/GA AVINEW strain, at least	5.5 $\log_{10}$ EID_{50}
Excipient	q.s. 1 dose

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for oral and ocular administration and for spraying

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens

6. INDICATION(S)

Active immunisation of chickens against Newcastle disease

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Ocular, oculo-nasal and oral route.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp.:
After reconstitution: use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

Disinfect empty bottles or bottles containing unused product before discarding.
Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4207

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1,000-dose bottle
2,000-dose bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AVINEW

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1,000 doses
2,000-doses

4. ROUTE(S) OF ADMINISTRATION

Ocular, oculo-nasal or oral route.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

Exp.:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Chickens
Read package leaflet before use.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
AVINEW

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 for the batch release:
MERIAL Laboratoire de Porte des Alpes, 99 rue de l'aviation, 69800 SAINT-PRIEST, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Each dose of reconstituted vaccine contains:

Live Newcastle disease virus, VG/GA AVINEW strain, at least	5.5 $\log_{10}$ EID_{50}
Excipient	q.s. 1 dose

EID50: Egg Infective Dose 50 per cent.

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

In future layer and breeder pullets, refer to the leaflet of the inactivated booster vaccine.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (broiler, future layer and future breeder pullets)

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

- 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.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store between 2°C and 8°C, protected from light.
After reconstitution: use within 2 hours.

12. SPECIAL WARNING(S)

- 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.
- Vaccinate healthy birds only.
- Apply the usual aseptic procedures.
- 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.
- Vaccination of chickens in lay is not recommended.
- 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.
- No side-effect has been observed following administration of 10 times the recommended dose of vaccine.
- 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.

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

IMMUNOLOGICAL PROPERTIES
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.

For veterinary use

Approved: 16 November 2018