ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avinew Fizz effervescent tablet for chickens and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Live Newcastle disease virus, strain VG/GA-AVINEW: $5.5 – 7.0 \log_{10} EID_{50}$(*)

(*) EID_{50}: Egg Infective Dose 50%

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: 6 weeks (after vaccination).
Vaccination interval as indicated in section 3.9.

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 the full schedule, see the SPC 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 birds only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The 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.

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.

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 humans. Therefore, during preparation and administration of the vaccine suspension, wear personal protective equipment consisting of 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

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 the national competent authority via the national reporting system. See 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:
One administration by ocular route (eye drop application) or oculonasal route (spray application) from the age of one day.
In case of increased risk of Newcastle disease the vaccination scheme needs to be adapted according to advice from the authorities.
A second administration could then be applied by oral route (in drinking water application) at the age of 2 to 3 weeks. The minimal interval between two administrations should be two weeks.

In future layer and future breeder pullets:
Two administrations by ocular route (eye drop application), oculonasal route (spray application) or oral route (in 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 (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 disinfectants and/or antiseptics.
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 disinfectants and/or antiseptics. 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:* in drinking water use.
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:* oculonasal use (spraying).
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 unwanted effects have been observed following administration of a tenfold overdose of the vaccine.

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

To be completed nationally.

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 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 tests in broiler chickens and turkeys.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Presence of disinfectants and/or antiseptics in the water and/or equipment used for dissolution of tablets is not compatible with an effective vaccination.
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 ºC-8 ºC).
Do not keep unused tablets removed from the blister.
Keep the blisters in the outer carton.

5.4 Nature and composition of immediate packaging

Nature of primary packaging:
Polyamide - aluminium – PVC / aluminium blister

Nature of outer packaging:
Carton box

Pack sizes:
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

To be completed nationally

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box of 1 blister of 10 tablets of 1000 doses
Carton box of 10 blisters of 10 tablets of 1000 doses
Carton box of 1 blister of 10 tablets of 2000 doses
Carton box of 10 blisters of 10 tablets of 2000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avinew Fizz effervescent tablet

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:
Live Newcastle disease virus, strain VG/GA-AVINEW: 5.5 - 7.0 $\log_{10}$ EID_{50}

3. PACKAGE SIZE

10 x 1000 doses
100 x 1000 doses
10 x 2000 doses
100 x 2000 doses

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Chickens: ocular, oculonasal or in drinking water use.
Turkeys: oculonasal use

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days

8. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once reconstituted: use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not keep unused tablets removed from the blister.
Keep the blisters in the outer carton.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister of 10 tablets of 1000 doses
Blister of 10 tablets of 2000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avinew Fizz

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Live Newcastle disease virus, VG/GA-AVINEW

1000 d.
2000 d.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once reconstituted: use within 2 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Avinew Fizz effervescent tablet for chickens and turkeys

2. Composition

Each dose contains:

Active substance:
Live Newcastle disease virus, strain VG/GA-AVINEW: 5.5 -7.0 $\log_{10}$ EID_{50}(*)
(*) EID50: Egg Infective Dose 50%

Excipients:
Brilliant blue FCF (E 133)

Blue mottled, round tablet.

3. Target species

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

4. Indications for use

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: 6 weeks (after vaccination).
Vaccination interval as indicated in the section “Dosage”.

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 the full schedule, see the package 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. Special warnings

Special warnings:

Vaccinate healthy birds only

Special precautions for safe use in the target species:
The 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.

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.

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 humans. Therefore, during preparation and administration of the vaccine suspension, wear personal protective equipment consisting of respiratory and eye protection in compliance with current European standards. For more information, contact the manufacturer.
Hands should be washed and disinfected after vaccinating.

Laying birds:
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:
No unwanted effects have been observed following administration of a tenfold overdose of the vaccine.

Major incompatibilities:
Presence of disinfectants and/or antiseptics in the water and/or equipment used for dissolution of tablets is not compatible with an effective vaccination.
Do not mix with any other veterinary medicinal product.

7. Adverse events

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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

In broiler chickens:
One administration by ocular route (eye drop application) or oculo-nasal route (spray application) from the age of one day.

In case of increased risk of Newcastle disease the vaccination scheme needs to be adapted according to advice from the authorities.
A second administration could then be applied by oral route (in drinking water application) at the age of 2 to 3 weeks. The minimal interval between two administrations should be two weeks.

In future layer and future breeder pullets:
Two administrations by ocular route (eye drop application), oculonasal route (spray application) or oral route (in 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 (spray application) from the age of one day.

Method of administration:
To reconstitute and prepare the vaccine, use clean, cold water.
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 disinfectants and/or antiseptics. 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:* in drinking water use.
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:* oculonasal use (spraying).
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.

9. Advice on correct administration

Wait until complete dissolution of the tablets before using the vaccine suspension.
For the preparation and administration of the vaccine, use clean material free from disinfectants and/or antiseptics.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC-8 ºC).
Do not keep unused tablets removed from the blister.
Keep the blisters in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp.
Shelf life after reconstitution according to directions: 2 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

Pack sizes:
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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
To be completed nationally

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
F-69800 Saint Priest
France

17. Other information

The vaccine contains live Newcastle disease virus, strain 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 and in turkeys.

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