[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield ND lyophilisate for oculonasal suspension/use in drinking water for chickens and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Newcastle disease virus, strain La Sota, Live $10^{6.0}$ to $10^{7.0}$ $TCID_{50}$*

* $TCID_{50}$ = 50% Tissue culture infective dose

Excipients:

Qualitative composition of excipients and other constituents
Povidone K-25
Bacto peptone
Monosodium glutamate
Potassium dihydrogen phosphate
Potassium hydroxide
Dextran 40 000

Cream coloured lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chickens and turkeys.

3.2 Indications for use for each target species

For active immunisation of chickens to reduce mortality and clinical signs due to infection with Newcastle disease virus.
Onset of immunity: 21 days post vaccination.
Duration of immunity: 35 days post vaccination.

For active immunisation of turkeys to prevent mortality and clinical signs due to infection with Newcastle disease virus.
Onset of immunity: 21 days post vaccination.
Duration of immunity has not been established.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Maternally derived antibodies (MDA) can interfere with the development of active immunity. Where it is likely, for example, that a recent field infection or vaccination of the parent flock has stimulated a high antibody titre and consequently a high level of MDA**,** the vaccination programme should be planned accordingly.
It has been shown in laboratory studies that MDA interfere with vaccination by the spray and oral route and can result in up to 55% unprotected birds 3 - 4 weeks post vaccination. Better protection in these studies was seen by oculonasal delivery but the onset of immunity was delayed by a week.

Influence of MDA on vaccination in turkeys has not been investigated.

3.5 Special precautions for use

Special precautions for safe use in the target species:

All birds in the flock should be vaccinated at the same time.

The vaccine strain can spread to susceptible, unvaccinated birds for at least 10 days following vaccination. The spread does not induce clinical signs.
Vaccine virus can disseminate to the trachea, spleen, kidneys, lung, caecal tonsils, duodenum and brains of chickens without inducing pathological changes to these organs.

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

Care should be taken when handling and administering the vaccine.
Newcastle disease virus can cause a mild transient conjunctivitis in the person administering the vaccine. Personal protective equipment consisting of a mask and eye protection should be worn when handling the veterinary medicinal product.
Wash and disinfect hands after administration of the vaccine.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens

Very common (>1 animal / 10 animals treated):	Respiratory signs[a]

[a] After oculonasal use. These symptoms could last at least two weeks.

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 its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Chickens:
Vaccination during lay is safe when it is performed in laying chickens which are already immunised against Newcastle disease virus by vaccination.

Turkeys:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

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

Chickens: 1 dose by coarse spray or oculonasal use from the age of 1 day. The vaccine can be administered in drinking water at the time when birds are drinking continuously from the drinking system.

Turkeys: 1 dose by coarse spray, oculonasal use or in drinking water use from the age of 14 days.

Method of application depends on the epizootiological situation, age, category and number of animals.
The veterinarian should determine the optimum vaccination schedule according to the local situation taking into account the information provided in section 3.4.
It is extremely important that all birds receive the full dose of vaccine. Details presented below should be strictly followed to achieve this.
After reconstitution the vaccine appears as a clear to slightly opalescent suspension.

If prolonged immunity is required, chickens can be revaccinated after 35 days.
Revaccination in turkeys has not been investigated.

1. Oculonasal use
Reconstitute 1 000 doses of the vaccine in 100 ml distilled water.
A dose of reconstituted vaccine is 0.1 ml, i.e. two drops, irrespective of poultry age, weight and type.
Instil one drop into an eye and one drop into a nostril.

2. In drinking water use
Reconstitute the vaccine in cool and clean water without traces of chlorine, other disinfectants or impurities in a number of doses corresponding to the number of birds to be vaccinated.
The vaccine should be reconstituted immediately before use.
The volume of water for reconstitution depends on the age of the birds, the breed, the management practice and weather conditions.
In order to determine the quantity of water in which vaccine will be reconstituted for the vaccination of chickens in a younger age category (until the third week of life), the following guideline applies:

- multiplying the number of birds in the thousands with the day of life (e.g. 1 thousand chickens in the 7th day of life = 1 x 7 = 7 L)

It is important to reconstitute the vaccine in the amount of water which will be drunk within 1.5 - 2.5 hours (taking into account the different types of drinking systems for poultry).
In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to vaccination (depending on the air temperature).
Always make sure that there is food available when vaccinating. Birds will not drink if they have no food to eat. The drinking system should be clean, without traces of chlorine, other disinfectants or impurities.

3. Coarse spray
It is recommended to reconstitute 1 000 doses of the vaccine in 150 - 300 ml of distilled water. The number of doses to be used corresponds to the number of birds in the flock.
The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds, and will vary according to the age of the birds being vaccinated and the management system.

The reconstituted vaccine suspension should be spread evenly over the correct number of chickens, at a distance of 30 – 40 cm using a coarse spray, preferably when the chickens are sitting together in dim light. The spray apparatus should be free from sediments, corrosion and traces of disinfectants and ideally should be used for vaccination purposes only. During and after vaccination ventilation should be switched off in order to avoid turbulences.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Slightly open mouth breathing was seen very commonly 5 - 9 days post vaccination after application of a tenfold overdose by coarse spray; these symptoms disappeared within 10 days.

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

Official control authority batch release may be required for this product according to national requirements.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD06

To stimulate active immunity against Newcastle disease virus. In the absence of a field infection with Newcastle disease, efficacy by challenge was not demonstrated under field conditions.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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: 3 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 ºC - 8 ºC).
Protect from light.

5.4 Nature and composition of immediate packaging

The vaccine is filled into colourless glass vials (type I), which are closed with rubber stoppers and sealed with aluminium caps.

Pack sizes:
Cardboard or plastic box with 10 vials of 1 000 doses of vaccine.
Cardboard or plastic box with 10 vials of 2 500 doses of vaccine.
Cardboard or plastic box with 10 vials of 5 000 doses of vaccine.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Genera d.d.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}> <{DD month YYYY}.>

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

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month 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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard or plastic box with 10 vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield ND lyophilisate for oculonasal suspension/use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:
Newcastle disease virus, strain La Sota, Live $10^{6.0}$ to $10^{7.0}$ $TCID_{50}$

3. PACKAGE SIZE

10 x 1 000 doses
10 x 2 500 doses
10 x 5 000 doses

4. TARGET SPECIES

Chickens and turkeys

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oculonasal, spray or in drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days

8. EXPIRY DATE

Exp. {mm/yyyy}Once reconstituted use within 3 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Protect from light.

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

Genera d.d.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Glass vials with 1 000, 2 500 or 5 000 doses of vaccine}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield ND

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose contains:
Newcastle disease virus, strain La Sota, Live $10^{6.0}$ to $10^{7.0}$ $TCID_{50}$

1 000 doses
2 500 doses
5 000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 3 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Avishield ND lyophilisate for oculonasal suspension/use in drinking water for chickens and turkeys

2. Composition

Each dose contains:

Newcastle disease virus, strain La Sota, Live $10^{6.0}$ to $10^{7.0}$ $TCID_{50}$*

* $TCID_{50}$ = 50% Tissue culture infective dose

Cream coloured lyophilisate.

3. Target species

Chickens and turkeys.

4. Indications for use

For active immunisation of chickens to reduce mortality and clinical signs due to infection with Newcastle disease virus.
Onset of immunity: 21 days post vaccination.
Duration of immunity: 35 days post vaccination.

For active immunisation of turkeys to prevent mortality and clinical signs due to infection with Newcastle disease virus.
Onset of immunity: 21 days post vaccination.
Duration of immunity has not been established.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Maternally derived antibodies (MDA) can interfere with the development of active immunity. Where it is likely, for example, that a recent field infection or vaccination of the parent flock has stimulated a high antibody titre and consequently a high level of MDA**,** the vaccination programme should be planned accordingly.
It has been shown in laboratory studies that MDA interfere with vaccination by the spray and oral route and can result in up to 55% unprotected birds 3 - 4 weeks post vaccination. Better protection in these studies was seen by oculonasal delivery but the onset of immunity was delayed by a week.

Influence of MDA on vaccination in turkeys has not been investigated.

Special precautions for safe use in the target species:
All birds in the flock should be vaccinated at the same time.
The vaccine strain can spread to susceptible, unvaccinated birds for at least 10 days following vaccination. The spread does not induce clinical signs. Vaccine virus can disseminate to the trachea, spleen, kidneys, lung, caecal tonsils, duodenum and brains of chickens without inducing pathological changes to these organs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken when handling and administering the vaccine.
Newcastle disease virus can cause a mild transient conjunctivitis in the person administering the vaccine. Personal protective equipment consisting of a mask and eye protection should be worn when handling the veterinary medicinal product.
Wash and disinfect hands after administration of the vaccine.

Laying birds:
Chickens:
Vaccination during lay is safe when it is performed in laying chickens which are already immunised against Newcastle disease virus by vaccination.

Turkeys:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

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:
Slightly open mouth breathing was seen very commonly 5 - 9 days post vaccination after application of a tenfold overdose by coarse spray; these symptoms disappeared within 10 days.

Special restrictions for use and special conditions for use:
Official control authority batch release may be required for this product according to national requirements.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Respiratory signs[a]

[a] After oculonasal use. These symptoms could last at least two weeks.

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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Chickens: 1 dose by coarse spray or oculonasal use from the age of 1 day. The vaccine can be administered in drinking water at the time when birds are drinking continuously from the drinking system.
Turkeys: 1 dose by coarse spray, oculonasal use or in drinking water use from the age of 14 days.

Method of application depends on the epizootiological situation, age category and number of animals. The veterinarian should determine the optimum vaccination schedule according to the local situation taking into account the information provided in the section "Special warnings".
It is extremely important that all birds receive the full dose of vaccine. Details presented below should be strictly followed to achieve this.

If prolonged immunity is required, the chickens can be revaccinated after 35 days.
Revaccination in turkeys has not been investigated.

9. Advice on correct administration

After reconstitution the vaccine appears as a clear to slightly opalescent suspension.

1. Oculonasal use
Reconstitute 1 000 doses of the vaccine in 100 ml distilled water.
A dose of reconstituted vaccine is 0.1 ml, i.e. two drops, irrespective of poultry age, weight and type.
Instil one drop into an eye and one drop into a nostril.

2. In drinking water use
Reconstitute the vaccine in cool and clean water without traces of chlorine, other disinfectants or impurities in a number of doses corresponding to the number of birds to be vaccinated.
The vaccine should be reconstituted immediately before use.
The volume of water for reconstitution depends on the age of the birds, the breed, the management practice and weather conditions.
In order to determine the quantity of water in which vaccine will be reconstituted for the vaccination of chickens in a younger age category (until the third week of life), the following guideline applies:

- multiplying the number of birds in the thousands with the day of life (e.g. 1 thousand chickens in the 7th day of life = 1 x 7 = 7 L)

It is important to reconstitute the vaccine in the amount of water which will be drunk within 1.5 - 2.5 hours (taking into account the different types of drinking systems for poultry).
In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to vaccination (depending on the air temperature).
Always make sure that there is food available when vaccinating. Birds will not drink if they have no food to eat. The drinking system should be clean, without traces of chlorine, other disinfectants or impurities.

3. Coarse spray
It is recommended to reconstitute 1 000 doses of the vaccine in 150 - 300 ml of distilled water. The number of doses to be used corresponds to the number of birds in the flock.
The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds, and will vary according to the age of the birds being vaccinated and the management system.
The reconstituted vaccine suspension should be spread evenly over the correct number of chickens, at a distance of 30 – 40 cm using a coarse spray, preferably when the chickens are sitting together in dim light. The spray apparatus should be free from sediments, corrosion and traces of disinfectants and ideally should be used for vaccination purposes only. During and after vaccination ventilation should be switched off in order to avoid turbulences.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 ºC - 8 ºC). Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 3 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 or pharmacist 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

MA number:

Pack sizes:
Cardboard or plastic box with 10 vials of 1 000 doses of vaccine.
Cardboard or plastic box with 10 vials of 2 500 doses of vaccine.
Cardboard or plastic box with 10 vials of 5 000 doses of vaccine.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month 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 manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:

Genera d.d.
Svetonedeljska cesta 2, Kalinovica
10436 Rakov Potok
Croatia
<Tel: >

<Local representatives and contact details to report suspected adverse reactions:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder. >

17. Other information

The vaccine stimulates active immunity against Newcastle disease virus.
In the absence of a field infection with Newcastle disease, efficacy by challenge was not demonstrated under field conditions.