[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield ND B1 lyophilisate for oculonasal suspension/use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:
Active substance:
Newcastle disease virus, strain B1 Hitchner, 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

Chicken (broilers, pullets future layers/breeders).

3.2 Indications for use for each target species

For active immunisation of chicken (broilers, pullets future layers/breeders) to reduce mortality and clinical signs due to infection with Newcastle disease virus.
Onset of immunity: 3 weeks post vaccination.
Duration of immunity: 5 weeks post vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
Maternally derived antibodies (MDA) can interfere with the development of active immunity. In flocks where high levels of MDAs are expected, vaccination programme should be planned accordingly.

3.5 Special precautions for use

Special precautions for safe use in the target species:

All the 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. The vaccine strain can spread to non-target susceptible species. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.
The 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 well-fitting masks and eye protection to European standards should be worn when handling the veterinary medicinal product. Personnel involved in attending vaccinated chickens should follow general hygiene principles (washing/disinfecting hands, changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials litter from recently vaccinated chickens.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chicken (broilers, pullets future layers/breeders):

Very common (>1 animal / 10 animals treated):	Respiratory signs[a] (e.g. Tracheal rales)

[a] After eye/nasal drop administration. These signs 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:
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

Oculonasal use (spray or eye/nasal drop): from one day of age.
In drinking water use: from 7 days of age.
One dose per chicken.

The method of application depends on the epizootiological situation, age category and number of animals.
After reconstitution the vaccine appears as a clear to slightly opalescent suspension.

1. Eye/nasal drop
Reconsitute 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.
For chickens aged from 1 to 14 days of smaller breeds, 4 drops of 25 µl should be used. Administer one drop in each eye (0.05 ml altogether) and then one drop in each nostril (0.05 ml altogether).

2. In drinking water use
Reconstiture 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. Where the number of birds is between the standard dosages, the next higher dosage should be used.
The vaccine should be reconstituted immediately before use.
Measure the correct volume of water for the number of birds to be vaccinated. The volume of water depends on the age of the birds, breed, management practice and weather conditions. In order to determine the quantity of water in which vaccine will be reconstituted, measure the volume of water consumed within a two hours period one day before vaccination.
The vaccine should be reconstituted in the amount of water which will be drunk within 1.5 to 2.0 hours (taking into account the different types of drinking systems for poultry).
As a guideline for younger chickens (until 3rd week of life), apply the reconstituted vaccine to cold and fresh water at the rate of 1 000 doses of vaccine to 1 litre of water per day of age for 1 000 chickens, e.g. 7 litres would be needed for 1 000 chickens of 7 days old.
In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to vaccination (drinking behaviour of the birds varies, depending on the air temperature, type of birds, breed, management, weather conditions).
The drinking system should work properly and should be clean, without traces of chlorine, other disinfectants or impurities.
If needed, turn the lights down low when the water supply is turned off. After the vaccine is added to the drinking water, increase the light. Increased light intensity will stimulate the birds to look for food and water.
Once the vaccine has been consumed, resume management practices as normal. This approach to vaccination will ensure a more even vaccination of the flock and will be less stressful to the birds. Performance should therefore be less adversely affected.

3. Coarse spray
It is recommended to reconstitue 1 000 doses of the vaccine in 150 - 300 ml of distilled water. The number of doses reconstituted corresponds to the number of birds in a 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 (targeted average droplet size of 150 - 170 microns), preferably when the chickens are sitting together in dim light.

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

Slightly open mouth breathing was seen very commonly 8-12 days post vaccination after application of a tenfold overdose by coarse spray in a laboratory study; these signs disappeared within 12 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

<to be completed nationally>

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD06

To stimulate active immunity against Newcastle disease virus in chickens**.**

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 and transport refrigerated (2 °C – 8 °C).
Do not freeze.
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 brombutyl rubber stoppers and sealed with aluminium caps.

Pack sizes:
Carton with 10 vials of 1 000 doses of vaccine.
Carton with 10 vials of 2 500 doses of vaccine.
Carton 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

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{ carton with 10 vials of 1 000 or 2 500 or 5 000 doses }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield ND B1 lyophilisate for oculonasal suspension/use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:
Newcastle disease virus, strain B1 Hitchner, 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

Chicken (broilers, pullets future layers/breeders)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oculonasal use (spray or eye/nasal drop) or in drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 ºC - 8 ºC).
Do not freeze.
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

{ label of vials with 1 000 or 2 500 or 5 000 doses }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield ND B1

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose contains:
Newcastle disease virus, strain B1 Hitchner, Live $10^{6.0}$ to $10^{7.0}$ $TCID_{50}$/dose

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 B1 lyophilisate for oculonasal suspension/use in drinking water for chickens

2. Composition

Each dose contains:

Active substance:
Newcastle disease virus, strain B1 Hitchner, Live $10^{6.0}$ to $10^{7.0}$ $TCID_{50}$*

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

Cream coloured lyophilisate.

3. Target species

Chicken (broilers, pullets future layers/breeders).

4. Indications for use

For active immunisation of chicken (broilers, pullets future layers/breeders) to reduce mortality and clinical signs due to infection with Newcastle disease virus.
Onset of immunity: 3 weeks post vaccination.
Duration of immunity: 5 weeks post vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
Maternally derived antibodies (MDA) can interfere with the development of active immunity.
In flocks where high levels of MDAs are expected, vaccination programme should be planned accordingly.

Special precautions for safe use in the target species:
All the 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. The vaccine strain can spread to non-target susceptible species. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.
The 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 well-fitting masks and eye protection to European standards should be worn when handling the veterinary medicinal product. Personnel involved in attending vaccinated chickens should follow general hygiene principles (washing/disinfecting hands, changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials litter from recently vaccinated chickens.

Laying birds:
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 8-12 days post vaccination after application of a tenfold overdose by coarse spray in laboratory study; these signs disappeared within 12 days.

<Special restrictions for use and special conditions for use:>
<to be completed nationally>

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

7. Adverse events

Chicken (broilers, pullets future layers/breeders):

Very common (>1 animal / 10 animals treated):	Respiratory signs[a] (e.g. Tracheal rales)

[a] After eye/nasal drop administration. These signs 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 its local representative> 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

Oculonasal use (spray or eye/nasal drop): from one day of age.
In drinking water use: from 7 days of age.
One dose per chicken.

The method of application depends on the epizootiological situation, age, category and number of animals.

9. Advice on correct administration

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

1. Eye/nasal drop
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.
For chickens aged from 1 to 14 days of smaller breeds, 4 drops of 25 µl should be used. Administer one drop in each eye (0.05 ml altogether) and then one drop in each nostril (0.05 ml altogether).

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. Where the number of birds is between the standard dosages, the next higher dosage should be used.
The vaccine should be reconstituted immediately before use.
Measure the correct volume of water for the number of birds to be vaccinated. The volume of water depends on the age of the birds, breed, management practice and weather conditions. In order to determine the quantity of water in which vaccine will be reconstituted, measure the volume of water consumed within a two hours period one day before vaccination.
The vaccine should be reconstituted in the amount of water which will be drunk within 1.5 to 2.0 hours (taking into account the different types of drinking systems for poultry).
As a guideline for younger chickens (until 3rd week of life), apply the reconstituted vaccine to cold and fresh water at the rate of 1 000 doses of vaccine to 1 litre of water per day of age for 1 000 chickens, e.g. 7 litres would be needed for 1 000 chickens of 7 days old.
In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to vaccination (drinking behaviour of the birds varies, depending on the air temperature, type of birds, breed, management, weather conditions).
The drinking system should work properly and should be clean, without traces of chlorine, other disinfectants or impurities.
If needed, turn the lights down low when the water supply is turned off. After vaccine is added to the drinking water, increase the light. Increased light intensity will stimulate the birds to look for food and water.
Once the vaccine has been consumed, resume management practices as normal. This approach to vaccination will ensure a more even vaccination of the flock and will be less stressful to the birds. Performance should therefore be less adversely affected.

3. Coarse spray
It is recommended to reconstitue 1 000 doses of the vaccine in 150 - 300 ml of distilled water. The number of doses reconstitutedcorresponds to the number of birds in a 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 (targeted average droplet size of 150 - 170 microns), preferably when the chickens are sitting together in dim light.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerate (2 ºC - 8 ºC).
Do not freeze.
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:
Carton with 10 vials of 1 000 doses of vaccine.
Carton with 10 vials of 2 500 doses of vaccine.
Carton 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

DD/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 manufacturer responsible for batch release <and contact details to report suspected adverse events>:

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

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

<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 chickens.