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

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension/use in drinking water

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens and turkeys

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oculonasal, spray or in drinking water use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {dd mm yy}
Once reconstituted use within 3 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Protect from light.

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

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. To be supplied only on veterinary prescription.
Administration by a veterinary surgeon or under their direct responsibility.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Genera Inc.
Svetonedeljska cesta 2, Kalinovica
10436 Rakov Potok
Croatia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43676/4000

17. MANUFACTURER'S BATCH NUMBER

Lot

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

1,000 doses
2,500 doses
5,000 doses

4. ROUTE(S) OF ADMINISTRATION

Oculonasal, spray or in drinking water use

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {dd mm yy}
Once reconstituted use within 3 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Genera Inc.
Svetonedeljska cesta 2, Kalinovica
10436 Rakov Potok
Croatia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

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

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

Lyophilisate for oculonasal suspension/use in drinking water.
Cream coloured lyophilisate.

4. INDICATION(S)

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 investigated.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Respiratory disturbances after oculonasal use occur very commonly. These symptoms could last at least two weeks.
The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chickens and turkeys.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 for each target species”.
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

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 the eye and one drop into the nose opening.

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 PERIOD

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 and carboard or plastic box after EXP.
Shelf life after reconstitution according to directions: 3 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.

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

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.

Lay:
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 (symptoms, emergency procedures, 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.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2021

15. 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.
For animal treatment only.
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.

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

Approved 25 February 2021