ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{carton with 10 vials of 1000 or 2500 or 5000 doses }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension/use in drinking water

4. PACKAGE SIZE

10 x 1000 doses
10 x 2500 doses
10 x 5000 doses

5. TARGET SPECIES

Chickens (broilers and future layers/breeders)

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oculonasal, spray or drinking water administration
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
Once reconstituted use within 3 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL 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

Local representative in UK:
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, UK.

16. MARKETING AUTHORISATION NUMBER

Vm 43676/4003

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{label of vials with 1000 or 2500 or 5000 doses }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

1000 doses
2500 doses
5000 doses

4. ROUTE(S) OF ADMINISTRATION

Oculonasal, spray or drinking water

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
Once reconstituted use within 3 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

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

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

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

Each dose contains:
Live, lentogenic virus of Newcastle disease, strain Hitchner B1 $10^{6.0}$ 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 (broilers and 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. ADVERSE REACTIONS

Respiratory disturbances such as tracheal rales occur very commonly after intranasal/ocular route of administration. These signs 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 (broilers and future layers/breeders)

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

Vaccination:
Coarse spray and oculonasal route: from one day of age
Drinking water route: from 7 days of age

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

1. Oculonasal administration
Suspend 1000 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 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. Drinking water administration
Suspend 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 suspended immediately before use.
Measure the correct volume of water for the number of birds to be vaccinated. The volume of water for reconstitution 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 suspended, measure the volume of water consumed within a two hours period one day before vaccination.
The vaccine should be dissolved 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 an orientation guide for younger chickens (until 3rd week of life), apply 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, 7 day old chickens.
In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to immunisation (birds drinking behaviour 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 is turned off. After vaccine is in drinking system, increase 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. Spray administration
It is recommended to resuspend 1000 doses of the vaccine in 150 - 300 ml of distilled water. The number of doses diluted 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton.
Shelf life after reconstitution according to directions: 3 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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 use in animals:
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.

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

Incompatibilities
Do not mix with any other veterinary medicinal product

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

15. OTHER INFORMATION

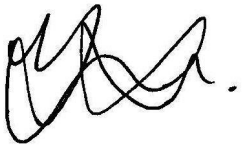
The vaccine stimulates active immunity against Newcastle disease virus in chickens.
For animal treatment only. To be supplied only on veterinary prescription.
Administration by a veterinary surgeon or under their direct responsibility.

Carton with 10 vials of 1000 doses of vaccine.
Carton with 10 vials of 2500 doses of vaccine.
Carton with 10 vials, of 5000 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.

Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, UK.



Approved: 05 October 2022