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: 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
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 at 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 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

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 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 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

Genera d.d.

7. MARKETING AUTHORISATION NUMBER

Vm 43676/4003

8. DATE OF FIRST AUTHORISATION

29 March 2018

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

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

GB: Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 03 December 2025

Gavin Hall