

[Version 9.1, 11/2024]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviGate ND QV4 lyophilisate for ocular/nasal suspension/use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:

Newcastle disease virus, strain QV4, live $10^{6.0}$ to $10^{7.0}$ EID₅₀*

*50% infective dose in embryonated eggs

Excipients:

Qualitative composition of excipients and other constituents
Dextran 40
Povidone
Peptone
Sodium L-glutamate monohydrate
Potassium dihydrogen phosphate
Potassium hydroxide
Water for injections

Whitish to off-white lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chicken (broiler, future layer and future breeder)

3.2 Indications for use for each target species

For active immunisation of chicks from one-day-old onwards to prevent mortality and reduce clinical signs caused by Newcastle disease (ND) virus.

Onset of immunity: 3 weeks after vaccination.

Duration of immunity: 6 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Vaccinated chickens may excrete the vaccine strain at least 28 days following vaccination. The vaccine strain can spread to susceptible, unvaccinated birds. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible birds. Direct contact between vaccinated and unvaccinated birds must be avoided during at least 28 days following vaccination. Spread of the vaccine to non-vaccinated birds does not cause clinical symptoms or disease. 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:

The vaccine may cause mild, transient conjunctivitis in humans. Since this vaccine has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process. These include personal protective equipment consisting of gloves and goggles / face shields that should be worn when handling the veterinary medicinal product and washing and disinfecting hands after administration of the vaccine. Personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated chickens.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chicken (broiler, future layer and future breeder):

None known.

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 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

The safety of the veterinary medicinal product has not been established during 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

For ocular use or in drinking water use.

The vaccine can be given to 1-day-old and older chickens as ocular use by dropping into the eyes and nares or by coarse spray. The vaccine can be administered to 7-day and older chickens by drinking water. In order to minimise stress to the birds during hot weather it is preferable to carry out vaccination early in the day at the coolest time.

Ocular use:

For administration by eye-drop it is recommended to use a pipet calibrated to deliver one dose of reconstituted vaccine of 0.05 mL. Use 50 mL cool distilled water or fresh, cool, dechlorinated tap

water per 1 000 doses for reconstitution of the vaccine. Mix the water containing the vaccine well before use.

For administration by coarse spray using a handheld or semi-automatic device, in a spray cabinet or inline automatic sprayer, ensure that the equipment is clean and free of disinfectant remnants or sediments. Apply coarse spray only. The droplets should be at least 100 to 150 micrometers in size. Calculate the volume of water required to vaccinate the birds according to nozzle used and other parameters following the instructions from the supplier of the device.

For manual or semi-automatic spray, 200 mL of water per 1 000 doses is suggested. The 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. Radiant heaters and ventilation should be switched off during spraying.

For administration in a spray cabinet or inline automatic sprayer, install a suitable nozzle size and adjust pressure as needed. Adjust the spray vaccinator according to the size of the chick boxes and the speed of the conveyor belt. Check regularly that the total surface of the chick box is uniformly and fully covered by spray e.g. by placing absorbent paper inside an empty chick box. Leave the chicks in the boxes for at least 20 minutes after spraying, to optimise the effect of preening and allowing them to dry.

In drinking water use for future layers and future breeder chickens:

One dose of the vaccine should be administered by drinking water from 7 days of age.

Water should be withheld prior to vaccination to make the chickens thirsty. The period for water withdrawal is dependent on the climate. Water withholding should be kept as short as possible with a minimum of 30 minutes.

The vaccine should be reconstituted in the dechlorinated drinking water or distilled water. The amount of water should be calculated based on the average water consumption of the flock in the previous 4 days before vaccination. Calculate the amount of water needed so that the vaccine is consumed within 2 hours at most.

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

No adverse reactions were observed after the administration of a 10-fold overdose.

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

The vaccine is intended to stimulate active immunity against Newcastle disease virus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing other substances used in drinking water.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.

Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C–8 °C).

Do not freeze.

Protect from light.

5.4 Nature and composition of immediate packaging

Glass vials (type I) containing 1 000, 2 500 or 5 000 doses, closed with a rubber stopper and sealed with an aluminium cap.

Carton box with 10 vials of 1 000 doses

Carton box with 10 vials of 2 500 doses

Carton box with 10 vials of 5 000 doses

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

Huvepharma

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

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX II
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON BOX WITH 10 VIALS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviGate ND QV4 lyophilisate for ocular nasal suspension/use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Newcastle disease virus, strain QV4, live $10^{6.0}$ to $10^{7.0}$ EID₅₀/dose

3. PACKAGE SIZE

10 x 1 000 doses

10 x 2 500 doses

10 x 5 000 doses

4. TARGET SPECIES

Chicken

5. ROUTES OF ADMINISTRATION

For ocular nasal use or in drinking water use

6. WITHDRAWAL PERIODS

Withdrawal periods: 0 days.

7. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted, use within 2 hours.

8. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2°C–8°C).

Do not freeze.

Protect from light.

9. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

10. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

11. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

12. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma

13. MARKETING AUTHORISATION NUMBERS

14. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
GLASS VIAL OF 1 000 OR 2 500 OR 5 000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AviGate ND QV4

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Newcastle disease virus, strain QV4, live $10^{6.0}$ to $10^{7.0}$ EID₅₀/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 2 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AviGate ND QV4 lyophilisate for ocular/nasal suspension/use in drinking water for chicken.

2. Composition

Each dose contains:

Active substance:

Newcastle disease virus, strain QV4, live $10^{6.0}$ to $10^{7.0}$ EID₅₀*

*50% infective dose in embryonated eggs

Whitish to off-white lyophilisate.

3. Target species

Chicken (broiler, future layer and future breeder)

4. Indications for use

For active immunisation of chicks from one-day-old onwards to prevent mortality and reduce clinical signs caused by Newcastle disease (ND) virus.

Onset of immunity: 3 weeks after vaccination.

Duration of immunity: 6 weeks after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

Vaccinated chickens may excrete the vaccine strain at least 28 days following vaccination. The vaccine strain can spread to susceptible, unvaccinated birds. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible birds. Direct contact between vaccinated and unvaccinated birds must be avoided during at least 28 days following vaccination. Spread of the vaccine to non-vaccinated birds does not cause clinical symptoms or disease. 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:

The vaccine may cause mild, transient conjunctivitis in humans. Since this vaccine has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process. These include personal protective

equipment consisting of gloves and goggles / face shields that should be worn when handling the veterinary medicinal product and washing and disinfecting hands after administration of the vaccine. Personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated chickens.

Laying birds:

The safety of the veterinary medicinal product has not been established during 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:

No adverse reactions were observed after the administration of a 10-fold overdose.

<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.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing other substances used in drinking water.

7. Adverse events

Chicken (broiler, future layer and future breeder):

None known.

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 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

For ocular use or in drinking water use.

The vaccine can be given to 1-day-old and older chickens as ocular administration by dropping into the eyes and nares or by coarse spray. The vaccine can be administered to 7-day and older chickens by drinking water. In order to minimise stress to the birds during hot weather it is preferable to carry out vaccination early in the day at the coolest time.

9. Advice on correct administration

Ocular application:

For administration by eye-drop it is recommended to use a pipet calibrated to deliver one dose of reconstituted vaccine of 0.05 mL. Use 50 mL cool distilled water or fresh, cool, dechlorinated tap

water per 1 000 doses for reconstitution of the vaccine. Mix the water containing the vaccine well before use.

For administration by coarse spray using a handheld or semi-automatic device, in a spray cabinet or inline automatic sprayer, ensure that the equipment is clean and free of disinfectant remnants or sediments. Apply coarse spray only. The droplets should be at least 100 to 150 micrometer in size. Calculate the volume of water required to vaccinate the birds according to nozzle used and other parameters following the instructions from the supplier of the device.

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In drinking water use for future layers and future breeder chickens:

One dose of the vaccine should be administered by drinking water from 7 days of age. Water should be withheld prior to vaccination to make the chickens thirsty. The period for water withdrawal is dependent on the climate. Water withholding should be kept as short as possible with a minimum of 30 minutes. The vaccine should be reconstituted in the dechlorinated tap water or in distilled water. The amount of water should be calculated based on the average water consumption of the flock in the previous 4 days before vaccination. Calculate the amount of water needed, so that the vaccine is consumed within 2 hours at most.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C–8 °C).

Do not freeze.

Protect from light.

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

Shelf life after reconstitution according to directions: 2 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

Pack sizes:

10 x 1 000 doses

10 x 2 500 doses

10 x 5 000 doses

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD month YYYY}

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Huvepharma
Uitbreidingstraat 80
2600 Antwerp
Belgium
Tel: +32 3 2881849

Manufacturer responsible for batch release:

Biovet AD
39, Petar Rokov Street
Peshtera 4550
Bulgaria