ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VAXXON ND CLONE lyophilisate and solvent for oculonasal suspension for chickens
VAXXON ND CLONE lyophilisate for oculonasal suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance:
Newcastle disease virus, strain Clone, live attenuated: 6.0-7.5 $\log_{10}$ ELD_{50}*
*ELD_{50}: embryo lethal dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate
Sorbitol
Gelatin
Pea protein GT plus
Disodium hydrogen phosphate dihydrate
Solvent (for eye-drop use only)
Patent Blue V (E131)
Water for injections

Lyophilisate: whitish homogeneous.

Solvent: clear blue solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens

3.2 Indications for use for each target species

For the active immunisation of chickens (broilers, future layers and breeders) from one day of age to reduce mortality and clinical signs of disease caused by infection with Newcastle disease virus.

Onset of immunity: 3 weeks after vaccination
Duration of immunity: 8 weeks (broilers) and 10 weeks (future layers and breeders)

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Maternally derived antibodies (MDA) can significantly interfere with the development of active immunity.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccinated chickens may excrete the vaccine strain for at least 14 days following vaccination. The vaccine strain can spread to unvaccinated chickens. The spread does not induce clinical signs of disease but may lead to seroconversion. Special precautions should be taken to avoid spreading of the vaccine strain to other susceptible bird species.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The vaccine may cause mild conjunctivitis in humans. Personal protective equipment consisting of gloves and goggles / face shields should be worn when handling the veterinary medicinal product. Wash and disinfect hands after administration of the vaccine.

The vaccine strain can be found in the environment for up to 14 days. 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 chicken.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Chickens (broilers, future layers and breeders)

Very common (>1 animal / 10 animals treated):	Cough[1,2] Decreased activity[1,5] Head shake[1,5]
Common (1 to 10 animals / 100 animals treated):	Ruffled feathers[1,3] Reduced growth rate[1,4] Buccopharyngeal flutter[1,5]

[1]Broilers only
[2]Between the first and second week post-vaccination, for 1 to 4 days
[3]Between the second and third week post-vaccination, for 6 days
[4]Between the second and seventh week post-vaccination, for 2 to 33 days
[5]In the first week post-vaccination for 1 or 2 days.

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.

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

Administer 1 dose of reconstituted vaccine by coarse spray or by eye-drop to chickens from 1 day of age.

Eye-drop application
Reconstitute the vaccine vial containing 1000 doses in 30 ml of VAXXON SOLVENT supplied for use with the product. Shake the suspension. Connect the dropper supplied for use with the product and administer one drop (0.03 ml) to one nostril or one eye. Ensure that the drop is swallowed before freeing the bird.

Appearance after reconstitution: clear blue solution

Coarse spray application
The vaccine can be administered by coarse spray using a suitable device. See the manufacturer's instructions on disinfection and maintenance of the device. The spray device should deliver a drop size of at least 100-150 micrometres in size. Reconstitute the lyophilisate using water of good quality (e.g. free from chlorine and/or disinfectants). Measure the correct volume of water so that each bird receives one dose of the vaccine. This depends on the device used and the number of birds to be vaccinated.

Appearance after reconstitution: clear yellowish solution

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

Coughing, buccopharyngeal flutter, nasal discharge, head shake or dyspnoea may be observed between one and two weeks following the administration of a 10-fold overdose. These symptoms disappear after the second week post-vaccination without additional treatment.

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

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

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 of chicken from one day of age against Newcastle disease virus. The vaccine contains live attenuated Newcastle disease virus strain Clone.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product (eye drop).

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after reconstitution according to directions: 4 hours
Shelf life of the solvent: 5 years

5.3 Special precautions for storage

Lyophilisate:
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Solvent:
Store below 25 °C.
Do not freeze.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Type I glass vial containing 1000, 2000, or 2500 doses. The vial is closed with a rubber stopper and aluminium cap.

Solvent:
Polyethylene bottle containing 30 ml. The vial is closed with a rubber stopper and aluminium cap.

Packaging:
Cardboard box containing 10 vials of 1000 doses of the lyophilisate and cardboard box containing 10 bottles of 30 ml of VAXXON SOLVENT and 10 droppers.
Cardboard box containing 10 vials of 1000 doses of the lyophilisate.
Cardboard box containing 10 vials of 2000 doses of the lyophilisate.
Cardboard box containing 10 vials of 2500 doses of the lyophilisate.

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

Vaxxinova International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/326/001-004

8. DATE OF FIRST AUTHORISATION

22/11/2024

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*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (lyophilisate)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VAXXON ND CLONE lyophilisate for oculonasal suspension for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Live attenuated Newcastle disease virus (NDV) strain Clone: 6.0-7.5 $\log_{10}$ ELD_{50} per dose

3. PACKAGE SIZE

10 x 1000 doses
10 x 2000 doses
10 x 2500 doses

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oculonasal

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp {mm/yyyy}
Once reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated
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

Company logo

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/326/001 (lyophilisate: 10 vials of 1000 doses, solvent: 10 bottles of 30 ml)
EU/2/24/326/002 (lyophilisate: 10 vials of 1000 doses)
EU/2/24/326/003 (lyophilisate: 10 vials of 2000 doses)
EU/2/24/326/004 (lyophilisate: 10 vials of 2500 doses)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (solvent)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VAXXON SOLVENT oculonasal solvent for live poultry vaccines

2. STATEMENT OF ACTIVE SUBSTANCES

3. PACKAGE SIZE

10 x 30 ml

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oculonasal

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Do not freeze.

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

Company logo

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/326/001 (lyophilisate: 10 vials of 1000 doses, solvent: 10 bottles of 30 ml)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VAXXON ND CLONE

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1000 doses
2000 doses
2500 doses
NDV ≥6.0 $\log_{10}$ ELD_{50} per dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}
Once reconstituted use within 4 hours.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE OF THE SOLVENT

Polyethylene bottle label

1. NAME OF THE SOLVENT

VAXXON SOLVENT oculonasal solvent for live poultry vaccines
30 ml

2. TARGET SPECIES

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

4. EXPIRY DATE

Exp {mm/yyyy}

5. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C

6. NAME OF THE MARKETING AUTHORIZATION HOLDER

Company logo.

7. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

VAXXON ND CLONE lyophilisate for oculonasal suspension for chickens
VAXXON ND CLONE lyophilisate and solvent for oculonasal suspension for chickens

2. Composition

Each dose of reconstituted vaccine contains:

Active substance:
Newcastle disease virus, strain Clone, live attenuated: 6.0-7.5 $\log_{10}$ ELD_{50}*
*ELD_{50}: embryo lethal dose 50%

Lyophilisate: whitish homogeneous.
Solvent: clear blue solution.

3. Target species

Chickens

4. Indications for use

For the active immunisation of chickens (broilers, future layers and breeders) from one day of age to reduce mortality and clinical signs of disease caused by infection with Newcastle disease virus.

Onset of immunity: 3 weeks after vaccination
Duration of immunity: 8 weeks (broilers) and 10 weeks (future layers and breeders)

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Maternally derived antibodies (MDA) can significantly interfere with the development of active immunity.

Special precautions for safe use in the target species:
Vaccinated chicken may excrete the vaccine strain for at least 14 days following vaccination. The vaccine strain can spread to unvaccinated chickens. The spread does not induce clinical signs of disease but may lead to seroconversion. Special precautions should be taken to avoid spreading of the vaccine strain to other susceptible bird species.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The vaccine may cause mild conjunctivitis in humans. Personal protective equipment consisting of gloves and goggles / face shields should be worn when handling the veterinary medicinal product. Wash and disinfect hands after administration of the vaccine.

The vaccine strain can be found in the environment for up to 14 days. 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 chicken.

Laying birds:
The safety of the veterinary medicinal product has not been established during lay.

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:
Coughing, buccopharyngeal flutter, nasal discharge, head shake or dyspnoea may be observed between one and two weeks following the administration of a10-fold overdose. These symptoms disappear after the second week post-vaccination without additional treatment.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

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, except solvent supplied for use with the veterinary medicinal product (eye drop).

7. Adverse events

Chickens (broilers, future layers and breeders)

Very common (>1 animal / 10 animals treated):
Cough[1,2], decreased activity[1,5], head shake[1,5]

Common (1 to 10 animals / 100 animals treated):
Ruffled feathers[1,3], reduced growth rate[1,4], buccopharyngeal flutter[1,5]

[1]Broilers only
[2]Between the first and second week post-vaccination, for 1 to 4 days
[3]Between the second and third week post-vaccination, for 6 days
[4]Between the second and seventh week post-vaccination, for 2 to 33 days
[5]In the first week post-vaccination for 1 or 2 days.

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

Administer 1 dose of reconstituted vaccine by coarse spray or by eye-drop to chickens from 1 day of age.

9. Advice on correct administration

Eye-drop application
Reconstitute the vaccine vial containing 1000 doses in 30 ml of VAXXON SOLVENT supplied for use with the product. Shake the suspension. Connect the dropper supplied for use with the product and administer one drop (0.03 ml) to one nostril or one eye. Ensure that the drop is swallowed before freeing the bird.

Appearance after reconstitution: clear blue solution.

Coarse spray application
The vaccine can be administered by coarse spray using a suitable device. See the manufacturer's instructions on disinfection and maintenance of the device. The spray device should deliver a drop size of at least 100-150 micrometres in size. Reconstitute the lyophilisate using water of good quality (e.g. free from chlorine and/or disinfectants). Measure the correct volume of water so that each bird receives one dose of the vaccine. This depends on the device used and the number of birds to be vaccinated.

Appearance after reconstitution: clear yellowish solution.

10. Withdrawal periods

Zero days

11. Special storage precautions

Keep out of the sight and reach of children.

Lyophilisate:
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Solvent:
Store below 25 °C.
Do not freeze.

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: 4 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

EU/2/24/326/001-004
Cardboard box containing 10 vials of 1000 doses of the lyophilisate and cardboard box containing 10 vials of 30 ml of VAXXON SOLVENT and 10 droppers.
Cardboard box containing 10 vials of 1000 doses of the lyophilisate.
Cardboard box containing 10 vials of 2000 doses of the lyophilisate.
Cardboard box containing 10 vials of 2500 doses of the lyophilisate.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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:
Vaxxinova International B.V., Transistorweg 5, 6534AT Nijmegen, The Netherlands
Email: RA.EU@vaxxinova.com

Contact details to report suspected adverse reactions:
IZO S.r.l. a socio unico, Via San Zeno 99a, 25124 Brescia, Italy
Tel. 0039 030 2420583
Email: farmacovigilanza@izo.it

Manufacturer responsible for batch release:
IZO S.r.l. a socio unico, S.S. 234 per Cremona Km 28,2 – 27013, Chignolo Po (PV), Italy
Email: info.chignolo@vaxxinova.it

17. Other information

To stimulate active immunity of chickens from one day of age against Newcastle disease virus. The vaccine contains live attenuated Newcastle disease virus strain Clone.