[Version 9.1, 11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN NEWCASTLE HB1 lyophilisate for suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substances:

Newcastle disease virus, strain B1 Hitchner, Live 6.0 - 7.0 $\log_{10}$ EID_{50}*

* EID_{50} = 50% embryo-infective dose: the virus titre causing infection in 50% of the embryos inoculated with the virus.

Excipients:

Qualitative composition of excipients and other constituents
Disodium phosphate
NZ Amine
Sorbitol
Gelatin
Hydrolysed gelatin
Water for injections

Beige coloured freeze-dried pellet.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For the active immunisation of chickens against Newcastle disease (ND) to reduce clinical signs and mortality.

Onset of immunity after a single administration:	3 weeks after first vaccination.
Onset of immunity after booster administration:	3 weeks after second dose of vaccine.
Duration of immunity in future layers:	up to 10 weeks of age (after two administrations at day 1 and at day 21 of life respectively).
Duration of immunity in broilers:	up to 4 weeks of age.

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 chicken may excrete the vaccine strain up to 10 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided.

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

The vaccine strain can be found in the environment for up to 10 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 chickens.
In case of accidental spillage into eyes, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse reactions (frequency and seriousness)

Chickens:

Very common (>1 animal / 10 animals treated)	Respiratory tract disorder*

* up to 7 - 10 days after vaccination and then last for up to 5 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 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 route and dosage

One dose / chicken per oculonasal use, nebulisation use or in drinking water use.

Vaccination scheme:
Broilers: One single vaccination from the first day of life.
Future layers: First vaccination on the first day of life and administration of a second dose 3 weeks later.

Preparation of the vaccine:
Ensure that drinking water and all equipment used for vaccination (tubes, drinkers, spray equipment etc.) are carefully cleaned and do not contain any residues of detergents, disinfectants and metal ions.
Use the entire contents of opened containers in one single session.
Only prepare the quantity of vaccine that can be administered within 2 hours. The vaccine should be administered to birds immediately after reconstitution.
Protect the vaccine solution from direct sunlight and temperatures above 25°C.

Remove the aluminium cap from the vaccine vial. To dissolve the lyophilisate, the rubber stopper should be removed whilst the vial is immersed in a plastic measuring jug containing the required volume of clean cool water. The solubilized vaccine concentrate should then be added to the drinking system (oral administration), or filled into the spraying device (coarse spray administration) or into the dropper (oculonasal administration).

In drinking water use:
1. The desired number of vaccine doses should be dissolved in the amount of drinking water calculated upon previous water consumption of the birds to be immunised.
2. Drinking water should be withdrawn from birds for 2 - 4 hours prior to vaccination, depending on their age and the temperature of the environment.
3. To preserve virus activity, it is advised to dissolve 2 - 4 g skimmed milk powder or 20 - 40 ml skimmed milk per litre of calculated drinking water prior to reconstitution of the vaccine.
4. The number of available drinkers during vaccination to ensure that all birds have access to the vaccinated water.

Nebulisation use:
1. The quantity of water needed for spraying depends on various factors such as the animals age, housing, temperature, stock density and the spray equipment used to spray the vaccine.
2. The vaccine solution should be sprayed evenly over the correct number of birds, at a distance of 30 - 40 cm, preferably when the birds are sitting together in dim light.
3. For 1-day old chicks use 250 ml for 1 000 birds; for older birds use 500 ml for 1 000 birds and set the nozzle to produce coarse spray.
   For primary vaccination it is recommended to use coarse spray with a droplet size ≥ 100 µm and for revaccinations a droplet size between 50 – 80 µm (fine spray).
4. Switch off or reduce the air conditioning if possible when spraying and for approximately 20 - 30 minutes thereafter.

Oculonasal use:
1. For 1 000 birds, reconstitute the lyophilisate pellet corresponding to 1 000 doses in 50 ml of physiological saline solution or sterile distilled water.
2. Use a calibrated dropper to apply drops depending on the size of animals. One drop of 50 µl should be applied into one nostril or one eye.
   In case of chicks from 1 to 14 days old or smaller breeds, 25 µl-drops should be used. Two drops (one drop into one eye and one drop into one nostril) should be administered.

The following table provides some advice for oculonasal administration:

Vaccine solution	**1 - 14 days old chicks or smaller breeds**	**> 14 days old chickens**
Number of drops	2 drops	1 drop
Size of drops	25 µl	50 µl
Reconstitution	1 vial in 50 ml of physiological saline solution or sterile distilled water	

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

No other clinical signs than those mentioned under 3.6 were observed after administration of ten times the maximum dose via the recommended routes.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD06

The virus strain of this vaccine is a live and lentogenic NDV strain which stimulates active immunity against Newcastle disease.

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: 2 hours

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I glass vials of 10 and 20 ml, closed with bromobutyl rubber stoppers and sealed with aluminium caps with a purple lid.

Pack sizes:
Card board box with 1 vial of 1 000 doses
Card board box with 10 vials of 1 000 doses
Card board box with 1 vial of 5 000 doses
Card board 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 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

LABORATORIOS CALIER, S.A.

7. MARKETING AUTHORISATION NUMBER

8. DATE OF FIRST AUTHORISATION

{DD/MM/YYYY}

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Card board boxes with 1 vial, card board boxes with 10 vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN NEWCASTLE HB1 lyophilisate for suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:
Newcastle disease virus, strain B1 Hitchner, Live 6.0 - 7.0 $\log_{10}$ EID_{50}*

* EID_{50} (embryo infectious dose 50%)

3. PACKAGE SIZE

1x 1 000 doses
1x 5 000 doses
10x 1 000 doses
10x 5 000 doses

4. TARGET SPECIES

Chickens

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For oculonasal use, nebulisation use or in drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protect from light.
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

LABORATORIOS CALIER, S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Glass vial of 1 000 or 5 000 doses}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN NEWCASTLE HB1

2. QUANTITY PARTICULARS OF THE ACTIVE SUBSTANCES

NDV, strain B1 Hitchner, Live 6.0 - 7.0 $\log_{10}$ EID_{50}

1 000 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

PRIMUN NEWCASTLE HB1 lyophilisate for suspension for chickens

2. Composition

Each dose contains:

Active substances:
Newcastle disease virus, strain B1 Hitchner, Live 6.0 - 7.0 $\log_{10}$ EID_{50}*

* EID_{50} = embryo infectious dose 50%: the virus titre causing infection in 50% of the embryos inoculated with the virus.

Beige coloured freeze-dried pellet.

3. Target species

Chickens.

4. Indications for use

For the active immunisation of chickens against Newcastle disease (ND) to reduce clinical signs and mortality.

Onset of immunity after a single administration:	3 weeks after first vaccination.
Onset of immunity after booster administration:	3 weeks after second dose of vaccine.
Duration of immunity in future layers:	up to 10 weeks of age (after two administrations at day 1 and at day 21 of live respectively).
Duration of immunity in broilers:	up to 4 weeks of age.

5. Contraindications

None.

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
Vaccinated chicken may excrete the vaccine strain up to 10 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The vaccine strain can be found in the environment for up to 10 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 chickens.
In case of accidental spillage into eyes, seek medical advice immediately and show the package leaflet or the label to the physician.

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interactions 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 other clinical signs than those mentioned under the section "Adverse events" were observed after administration of ten times the maximum dose via the recommended routes.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:

Very common (>1 animal / 10 animals treated)	Respiratory tract disorder*

* up to 7 - 10 days after vaccination and then last for up to 5 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 <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

One dose /animal per oculonasal use, nebulisation use or in drinking water use.

Vaccination scheme:
Broilers: One single vaccination from the first day of life.
Future layers: First vaccination on the first day of life and administration of a second dose 3 weeks later.

9. Advice on correct administration

Ensure that drinking water and all equipment used for vaccination (tubes, drinkers, spray equipment etc.) are carefully cleaned and do not contain any residues of detergents, disinfectants and metal ions.
Use the entire contents of opened containers in one single session.
Only prepare the quantity of vaccine that can be administered within 2 hours. The vaccine should be administered to birds immediately after reconstitution.
Protect the vaccine solution from direct sunlight and temperatures above 25°C.

Remove the aluminium cap from the vaccine vial. To dissolve the lyophilisate, the rubber stopper should be removed whilst the vial is immersed in a plastic measuring jug containing the required volume of

clean cool water. The solubilized vaccine concentrate should then be added to the drinking system (oral administration), or filled into the spraying device (coarse spray administration) or into the dropper (oculonasal administration).

In drinking water use:

1. The desired number of vaccine doses should be dissolved in the amount of drinking water calculated upon previous water consumption of the birds to be immunised.
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3. To preserve virus activity, it is advised to dissolve 2 - 4 g skimmed milk powder or 20 - 40 ml skimmed milk per litre of calculated drinking water prior to reconstitution of the vaccine.
4. The number of available drinkers should be increased during vaccination to ensure that all birds have access to the vaccinated water.

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Reconstitution	1 vial in 50 ml of physiological saline solution or sterile distilled water	

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2°C – 8°C).
Protect from light.
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: 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 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

MA number(s)

Pack sizes:
Card board box with 1 vial of 1 000 doses
Card board box with 10 vials of 1 000 doses
Card board box with 1 vial of 5 000 doses
Card board box with 10 vials of 5 000 doses

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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 and manufacturer responsible for batch release:
LABORATORIOS CALIER, S.A.
c. Barcelonès, 26 Pla del Ramassar
08520 LES FRANQUESES DEL VALLES, (Barcelona)
SPAIN
Tel.: +34 938495133
E-mail: laboratorios@calier.es

Local representatives <and contact details to report suspected adverse events>:

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