

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN NEWCASTLE C30

Lyophilisate for suspension for chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substances:

Newcastle disease virus (NDV), strain NDV_CLS, live: 6.0 - 7.0 log₁₀ EID₅₀*

* EID₅₀ = 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

Lyophilisate for suspension

Appearance: 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 immunization of chickens against Newcastle disease (ND) to reduce clinical signs and mortality.

Onset of immunity: 3 weeks after 1st vaccination

Duration of immunity in future layers: up to 10 weeks of age (after 2 administrations at day 1 and at day 21)

Duration of immunity in broilers: up to 6 weeks of age (after 2 administrations at day 1 and at day 21)

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The presence of maternally derived antibodies (MDA) may interfere with the development of active immunity.

If a high titre of antibodies is probable due to field infection or recent vaccination of the mothers, and consequently, a high level of MDA in the progeny must be expected, the vaccination programme should be planned accordingly.

3.5 Special precautions for use

- Protect the vaccine solution from direct sunlight and temperatures above 25°C.
- Ensure that drinking water and all equipment used for vaccination (tubes, drinkers, 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.

Special precautions for safe use in the target species

Vaccinated chickens may excrete the vaccine strain for at least 10 days following vaccination. During this time, direct and indirect contact of immunosuppressed and unvaccinated chickens of all susceptible wild and domestic species with vaccinated chickens should be avoided.

It is recommended to vaccinate all birds on a site at the same time.

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

NDV may induce conjunctivitis in humans upon contact to eyes. Therefore, during spray vaccination eye and inhalation protection (face mask/visors) must be worn. Wash and disinfect hands and equipment after application.

In case of accidental spillage into eyes, rinse with water immediately, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Very common (>1 animal/ 10 animals treated)	Respiratory tract disorders*
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* May first occur up to 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

The safety of the veterinary medical 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.

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

Dosage: 1 dose / chicken.

Vaccination scheme:

Broilers and future layers:

1st vaccination on the 1st day of life and administration of a 2nd dose 3 weeks later.

Administration routes: oculonasal use, nebulisation use or in drinking water use

Remove the aluminium cap from the vaccine vial. To dissolve the vaccine pellet, 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 diluted 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 (oculo-nasal administration).

Oral administration via in drinking water use:

1. The number of vaccine doses should be dissolved in the amount of drinking water calculated upon previous water consumption of the birds to be immunized.
2. The number of doses should be rounded up for smaller flocks and dissolved accordingly.
3. Ensure that drinking water and all equipment used for vaccination (tubes, drinkers, etc.) are carefully cleaned and do not contain any residues of detergents, disinfectants or metal ions.
4. Drinking water should be withdrawn from birds for 2 - 4 hours prior to vaccination, depending on their age and the temperature of the environment.
5. To preserve virus activity, it is advised to dissolve 2 - 4 g skimmed milk powder per litre of calculated drinking water or skimmed milk (20 - 40 ml/litre of water), prior to dissolving the vaccine.
6. It is advised to increase the number of drinkers during vaccination. To ensure that all birds have access to the vaccinated water, it is advised to move birds around the drinkers in the first few minutes of vaccination. The birds should be supplied with fresh drinking water only after the medicated water has been entirely consumed.
7. The vaccine should be administered to birds immediately after reconstitution.

Spray administration

1. The vaccine should preferably be dissolved in distilled water or alternatively, in clean, cold water non-chlorinated and free from metal-ions.
2. The quantity of water needed for spraying depends on various factors such as animal age, housing, temperature, stock density and the apparatus used to spray the vaccine. Use only chlorine-free or distilled water.
3. The spray apparatus should be free from sediments, corrosion and traces of disinfectants (preferably used for vaccination purpose only).
4. The vaccine medicated water 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.
5. 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.

In the field, coarse spray (drop size $\geq 100 \mu\text{m}$) is recommended for primary vaccination and a droplet size between 50 – 80 μm (fine spray) for revaccinations.

6. Switch off or reduce the air conditioning, if possible, when spraying and for approximately 20 - 30 minutes thereafter.

Eye-drop administration:

1. For 1,000 birds, reconstitute the lyophilisate pellet corresponding to 1,000 doses into 50 ml of distilled water or alternatively in clean cold water non-chlorinated and free from metal ions.
2. Use a calibrated dropper to apply drops of 50 or 25 µl, depending on the size of the animals. One drop should be applied into one nostril or one eye. In case of administration of two drops, instil one drop into one eye and one drop into one of the nostrils.

In case of chicks from 1 to 14 days of age or smaller breeders, 25 µl-drops should be used. Two drops (one drop per eye or nostril) should be administered.

The following table provides some advice for oculo-nasal administration:

	AGE AND TYPE OF ANIMAL	
	1-14 days old or smaller breeds	> 14 days old
Number of drops	2 drops	1 drop
Size of the drop	25 µl	50 µl
Reconstitution	1 vial in 50 ml of sterile distilled water or in clean cold water non-chlorinated and free from metal ions.	

- Nasal route: Hold the dropper vertically and allow a drop of the solution to fall into one of the bird's nostrils. The beak of the chicken shall be kept closed, covering one nostril, deposit the drop in the other. Do not let go of the chicken until it has inhaled the drop. Avoid covering the nose of the chicken with the dropper tip. Ensure that the nasal drop is inhaled.
- Ocular route: Vaccination by eye drop method is conducted holding the dropper in a vertical position and allowing a full drop of vaccine to fall into the open eye of the bird. Hold the bird until the drop of vaccine disappears. Be careful not to harm the cornea with the tip of the dropper.

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

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Lyophilised vaccine:

1,000 and 5,000 doses in type I glass vials of 10 ml and 20 ml, closed with bromobutyl rubber stoppers and sealed with aluminium caps with a bottle green lid.

Packaging:

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 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

LABORATORIOS CALIER, S.A.

7. MARKETING AUTHORISATION NUMBER

8. DATE OF FIRST AUTHORISATION

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

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>).

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 C30 Lyophilisate for suspension for chickens

2. STATEMENT OF ACTIVE SUBSTANCES**Each dose contains:**

Newcastle Disease virus (NDV), strain NDV_CLS, live 6.0 -7.0 log₁₀ EID₅₀*

* EID₅₀ (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. INDICATIONS**6. ROUTES OF ADMINISTRATION**

For eye-drop, spray or drinking water administration

7. 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

{vial of 1,000 or 5,000 doses}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN NEWCASTLE C30 Lyophilisate for suspension for chickens

2. QUANTITY PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose contains:

Newcastle Disease virus (NDV), strain NDV_CLS, live 6.0 -7.0 log₁₀ EID₅₀

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}

Once reconstituted use within 2 hours

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

PRIMUN NEWCASTLE C30 Lyophilisate for suspension for chickens.

2. Composition

Each dose contains:

Active substances:

Newcastle Disease virus (NDV), strain NDV CLS, live	6.0 - 7.0 log ₁₀ EID ₅₀ *
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* EID₅₀ (embryo infectious dose 50%: the virus titre causing infection in 50% of the embryos inoculated with the virus)

Lyophilisate for suspension.

Appearance: beige coloured freeze-dried pellet.

3. Target species

Chickens.

4. Indications for use

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

Onset of immunity: 3 weeks after 1st vaccination.

Duration of immunity in future layers: up to 10 weeks of age (after 2 administrations at day 1 and at day 21)

Duration of immunity in broilers: up to 6 weeks of age (after 2 administrations at day 1 and at day 21)

5. Contraindications

None.

6. Special warnings

- Protect the vaccine solution from direct sunlight and temperatures above 25°C.

- Ensure that drinking water and all equipment used for vaccination (tubes, drinkers, 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.

Special warnings

Vaccinate healthy animals only.

The presence of maternally derived antibodies (MDA) may interfere with the development of active immunity.

If a high titre of antibodies is probable due to field infection or recent vaccination of the mothers, and consequently, a high level of MDA in the progeny must be expected, the vaccination programme should be planned accordingly.

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.

It is recommended to vaccinate all birds on a site at the same time.

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

NDV may induce conjunctivitis in humans upon contact to eyes. Therefore, during spray vaccination eye and inhalation protection (face mask/visors) must be worn. Wash and disinfect hands and equipment after application.

In case of accidental spillage into eyes, rinse with water immediately, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

Laying birds

The safety of the veterinary medical 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.

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 7. were observed after administration of ten times the maximum dose via the recommended routes.

Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products

7. Adverse events

Very common (>1 animal/ 10 animals treated)	Respiratory tract disorders*
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* May first occur up to 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

Dosage: 1 dose / chicken.

Vaccination scheme:

Broilers and future layers: 1st vaccination on the 1st day of life and administration of a 2nd dose 3 weeks later.

Administration route: oculonasal use, nebulisation use or in drinking water use.

9. Advice on correct administration

Administration route: oculonasal use, nebulisation use or in drinking water use

Remove the aluminium cap from the vaccine vial. To dissolve the vaccine pellet, 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 diluted 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 (oculo-nasal administration).

Oral administration via drinking water:

1. The number of vaccine doses should be dissolved in the amount of drinking water calculated upon previous water consumption of the birds to be immunized.
2. The number of doses should be rounded up for smaller flocks and dissolved accordingly.
3. Ensure that drinking water and all equipment used for vaccination (tubes, drinkers, etc.) are carefully cleaned and do not contain any residues of detergents, disinfectants or metal ions.
4. Drinking water should be withdrawn from birds for 2 - 4 hours prior to vaccination, depending on their age and the temperature of the environment.
5. To preserve virus activity, it is advised to dissolve 2 - 4 g skimmed milk powder per litre of calculated drinking water or skimmed milk (20 - 40 ml/litre of water), prior to dissolving the vaccine.
6. It is advised to increase the number of drinkers during vaccination. To ensure that all birds have access to the vaccinated water, it is advised to move birds around the drinkers in the first few minutes of vaccination. The birds should be supplied with fresh drinking water only after the medicated water has been entirely consumed.
7. The vaccine should be administered to birds immediately after reconstitution.

Spray administration:

1. The vaccine should preferably be dissolved in distilled water or alternatively, in clean, cold water non-chlorinated and free from metal-ions.
2. The quantity of water needed for spraying depends on various factors such as animal age, housing, temperature, stock density and the apparatus used to spray the vaccine. Use only chlorine-free or distilled water.
3. The spray apparatus should be free from sediments, corrosion and traces of disinfectants (preferably used for vaccination purpose only).
4. The vaccine medicated water 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.
5. 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.

In the field, coarse spray (drop size $\geq 100 \mu\text{m}$) is recommended for primary vaccination and a droplet size between 50 – 80 μm (fine spray) for revaccinations.

6. Switch off or reduce the air conditioning, if possible, when spraying and for approximately 20 - 30 minutes thereafter.

Eye-drop administration:

1. For 1,000 birds, reconstitute the lyophilisate pellet corresponding to 1,000 doses into 50 ml of distilled water or alternatively in clean, cold water non-chlorinated and free from metal ions.

2. Use a calibrated dropper to apply drops of 50 or 25 µl, depending on the size of the animals. One drop should be applied into one nostril or one eye. In case of administration of two drops, instil one drop into one eye and one drop into one of the nostrils. In case of chicks from 1 to 14 days of age or smaller breeds, 25 µl-drops should be used. Two drops (one drop per eye or nostril) should be administered.

The following table provides some advice for eye-drop administration:

	AGE AND TYPE OF ANIMAL	
	1-14 days old or smaller breeds	> 14 days old
Number of drops	2 drops	1 drop
Size of the drop	25 µl	50 µl
Reconstitution	1 vial in 50 ml sterile distilled water or clean, cold water non-chlorinated and free from metal ions	

- Nasal route: Hold the dropper vertically and allow a drop of the solution to fall into one of the bird's nostrils. The beak of the chicken shall be kept closed, covering one nostril, deposit the drop in the other. Do not let go of the chicken until it has inhaled the drop. Avoid covering the nose of the chicken with the dropper tip. Ensure that the nasal drop is inhaled.
- Ocular route: Vaccination by eye-drop method is conducted holding the dropper in a vertical position and allowing a full drop of vaccine to fall into the open eye of the bird. Hold the bird until the drop of vaccine disappears. Be careful not to harm the cornea with the tip of the dropper.

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.

Shelf life after reconstitution according to directions: 2 hours

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household water.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

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

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

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

17. Other information