

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 of reconstituted vaccine contains:

Active substance:

Live Newcastle disease virus (NDV), lentogenic strain NDV_HB1: 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:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

Appearance: beige coloured freeze-dried pellet

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

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

Onset of immunity after a single administration: 3 weeks after 1st vaccination.

Onset of immunity after booster administration: 3 weeks after 2nd dose of vaccine.

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

Duration of immunity in broilers: up to 4 weeks of age.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 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 use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

Slight respiratory symptoms may be noted very commonly in vaccinated birds 7 - 10 days after vaccination. All symptoms subside within about 5 days.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 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/or within 4 weeks before the start of the laying period.

4.8 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.

4.9 Amounts to be administered and administration route

Dosage: 1 dose / chicken

Vaccination scheme:

Broilers: 1 vaccination from the 1st day of life

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

Administration routes: oculo-nasal use, nebulisation use or 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 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 (oculo-nasal administration).

Oral administration via drinking water:

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 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 was entirely consumed.

7. The vaccine should be administered to birds immediately after reconstitution.

Spray method:

1. The vaccine should preferably be dissolved in distilled water or alternatively, in clean, cold water preferably non-chlorinated and free from metal-ions.
2. The quantity of water needed for spraying depends on various factors such as the animals 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 purposes 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 1000 birds; for older birds use 500 ml for 1000 birds and set the nozzle to produce coarse spray.
For primary vaccination in the field coarse spray (drop size $\geq 100 \mu\text{m}$) and for revaccinations a droplet size between 50 – 80 μm (fine spray) is recommended.
6. Switch off or reduce the air conditioning if possible when spraying and for approximately 20 - 30 minutes thereafter.

Oculo-nasal administration:

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

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 physiological saline solution or sterile distilled water	

- 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No other clinical signs than those mentioned under 4.6. were observed after administration of ten times the maximum dose via the recommended routes.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Live viral vaccines for domestic fowls. Newcastle disease virus (NDV, paramyxovirus 1).

ATCvet code: QI01AD06

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate

NZ Amine

Sorbitol

Gelatin

Hydrolysed gelatin

Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after reconstitution according to directions: 2 hours

6.4. Special precautions for storage

Store and transport refrigerated (2°C – 8°C).

Protect from light.

Do not freeze.

6.5 Nature and composition of immediate packaging

Lyophilised vaccine:

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

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, 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.

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 for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:

Live Newcastle Disease virus (NDV), lentogenic strain NDV_HB1, 6.0 -7.0 log₁₀ EID₅₀*

* EID₅₀ (embryo infectious dose 50%)

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

4. PACKAGE SIZE

1x 1,000 doses

1x 5,000 doses

10x 1,000 doses

10x 5,000 doses

5. TARGET SPECIES

Chickens

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Dosage: 1 dose / chicken

For oculo-nasal use, nebulisation use or drinking water use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once reconstituted: 2 hours

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

<Batch><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 HB1 Lyophilisate for suspension for chickens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose contains:

Live Newcastle Disease virus (NDV), lentogenic strain NDV_HB1, 6.0 -7.0 log₁₀ EID₅₀

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1,000 doses

5,000 doses

4. ROUTE(S) OF ADMINISTRATION

For oculo-nasal use, nebulisation use or drinking water use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP month/year

Once reconstituted: 2 hours

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

PRIMUN NEWCASTLE HB1 Lyophilisate for suspension for chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN NEWCASTLE HB1 Lyophilisate for suspension for chickens.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of reconstituted vaccine contains:

Active substance:

Live Newcastle Disease virus (NDV), lentogenic strain NDV_HB1 6.0 - 7.0 log₁₀ EID₅₀*

* EID₅₀ (embryo infectious dose 50%: the virus titre causing infection in 50% of the embryos inoculated with the virus)

Appearance: beige coloured freeze-dried pellet

4. INDICATION(S)

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

Onset of immunity after a single administration: 3 weeks after 1st vaccination.

Onset of immunity after booster administration: 3 weeks after 2nd dose of vaccine.

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

Duration of immunity in broilers: up to 4 weeks of age.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Slight respiratory symptoms may be noted very commonly in vaccinated birds 7 - 10 days after vaccination. All symptoms subside within about 5 days.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Chickens.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage: 1 dose /animal.

Vaccination scheme:

Broilers: 1 vaccination from the 1st day of life

Future layers: 1st vaccination on the 1st day of life and administration of a booster dose 3 weeks later.

Administration routes: oculo-nasal use, nebulisation use or drinking water use

9. ADVICE ON CORRECT ADMINISTRATION

Administration routes: oculo-nasal use, nebulisation use or 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 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 (oculo-nasal administration).

Oral administration via drinking water:

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 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 was entirely consumed.
7. The vaccine should be administered to birds immediately after reconstitution.

Spray method:

1. The vaccine should preferably be dissolved in distilled water or alternatively, in clean, cold water preferably non-chlorinated and free from metal-ions.
2. The quantity of water needed for spraying depends on various factors such as the animals 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 1000 birds; for older birds use 500 ml for 1000 birds and set the nozzle to produce coarse spray.

For primary vaccination in the field coarse spray (drop size $\geq 100 \mu\text{m}$) and for revaccinations a droplet size between 50 – 80 μm (fine spray) is recommended.
6. Switch off or reduce the air conditioning if possible when spraying and for approximately 20 - 30 minutes thereafter.

Oculo-nasal administration:

1. For 1,000 birds, reconstitute the lyophilisate pellet corresponding to 1,000 doses into 50 ml of physiological saline solution or sterile distilled water.

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 dissolution in 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 old or smaller breeds, 25 µl-drops should be used. Two drops (one drop per eye or nostril) should be administered then.

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 physiological saline solution or sterile distilled water	

- 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 PERIOD(S)

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.

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after reconstitution according to directions: 2 hours

12. SPECIAL WARNING(S)

- 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 for each target species:

None.

Special precautions for use in animals:

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:

The safety of the veterinary medical product has not been established during lay.

Do not use in birds in lay and/or 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 (symptoms, emergency procedures, antidotes):

No other clinical signs than those mentioned under 4.6. 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

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