1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN IB-ND DUO

Lyophilisate for suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substances:

Live Newcastle disease virus (NDV), lentogenic strain NDV_HB1: 6.0 - 7.0 $\log_{10}$ EID_{50}*

Live Infectious Bronchitis Virus (IBV), Massachusetts strain IBV_H120: 3.0 - 4.0 $\log_{10}$ EID_{50}*

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

Excipients:

For the 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) and Massachusetts serotype of Infectious Bronchitis (IB) 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 3 administrations at day 1, at week 3 and week 7, respectively)
Duration of immunity in broilers:	up to 6 weeks of age (after 2 administrations at day 1 and at week 3)

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 chickens may excrete the vaccine strain up to 18 days following vaccination. The vaccine strain can be found in the environment for at least 18 days.

The vaccine strains NDV_HB1 and IBV_H120 can spread to in-contact birds. Special precautions should be taken to avoid spreading of the vaccine strains to unvaccinated birds. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.

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 nebulisation 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.

4.6 Adverse reactions (frequency and seriousness)

Slight respiratory symptoms may be noted commonly in vaccinated birds 3 - 10 days after vaccination. All clinical signs 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)

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

Future layers: 1st vaccination on the 1st day of life, administration of a 2nd dose 3 weeks later and administration of a 3rd dose 4 weeks after 2nd administration (on 7th week).

Administration routes: oculo-nasal 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 vaccine solution should then be added to the drinking system (in drinking water use), or filled into the spraying device (nebulisation use) or into the dropper (oculo-nasal 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 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.

Nebulisation use:

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 spraying device should be free from sediments, corrosion and traces of disinfectants (preferably used for vaccination purpose only).
4. 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.
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 (droplet size ≥ 100 µm) 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.

Oculo-nasal administration:

1. For 1,000 birds, reconstitute the lyophilisate corresponding to 1,000 doses into 50 ml of sterile distilled water.
2. Use 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 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	

- 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, in this case the signs subside within about 10 days. In addition, complete ciliostasis was detected after the application of an overdose.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccines for domestic fowls. Newcastle disease virus (NDV) + avian infectious bronchitis virus (IBV).

ATCvet code: QI01AD11

The virus strains of this vaccine are a live and lentogenic NDV strain and a live IBV Massachusetts strain which stimulate active immunity against Newcastle disease and Infectious Bronchitis, respectively.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate

Potassium dihydrogen phosphate

Lactose monohydrate

Skimmed milk powder

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 2,000 doses in type I glass vials of 10 ml, closed with bromobutyl rubber stoppers and sealed with aluminium caps with bottle lid of mustard colour.

Packaging:

Card board box with 1 vial of 1,000 doses.
Plastic box with 10 vials of 1,000 doses.
Card board box with 1 vial of 2,000 doses.
Plastic box with 10 vials of 2,000 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

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8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

The manufacture, import, possession, sale, supply and/or use of PRIMUN IB-ND DUO is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use PRIMUN IB-ND DUO must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.