SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac NDW

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition

Live Newcastle Disease Virus, strain Ulster 2C

Quantitative composition

Active Substances:	Per dose
Live Newcastle Disease Virus; strain Ulster 2C	$10^{5.7}$- $10^{6.6}$ EID_{50}

Excipients:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for reconstitution for eye drops solution, nasal drops solution, oral solution or nebulisation solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens from one day of age.

4.2 Indications for use, specifying the target species

For active immunisation of chickens to reduce mortality and clinical signs due to infection with Newcastle Disease.

The onset of immunity is from three weeks post vaccination.

4.3 Contraindications

Do not vaccinate unhealthy birds.

4.4 Special warnings

Maternally derived antibody (MDA) can interfere with the development of active immunity. Where it is likely that recent field infection or vaccination of the parent flock has stimulated a high antibody titre and consequently a high

level of MDA, the timing of the vaccination programme should be planned accordingly.

4.5 Special precautions for use

i Special precautions for use in animals

None.

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

Live Newcastle disease virus may cause conjunctivitis in man. When using the vaccine, operators must protect eyes and nose by wearing goggles and a full-face mask, especially with spray method. An appropriate helmet with filtered air circulation may be used instead of goggles and a mask.

On completion, operators should wash and disinfect hands in an approved disinfectant.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay (breeding birds and/or within 4 weeks before the onset of the laying period)

4.8 Interaction with other medicinal products and other forms of interaction

Efficacy data is available which demonstrates that this vaccine can be administrated at least 10 days after the administration of live infectious bronchitis and Mareks disease vaccines in the Poulvac range by Zoetis.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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

Vaccination Schedule

Broilers:

For spray or eye/nose drop administration.

One dose per broiler chicken to be administered via spray or eye/nose drop from one day of age. An additional dose may be required for broilers or so called heavy roaster birds to be taken beyond 45 days of age at slaughter.

Future layers, Breeders:

One dose by spray or eye drop at one day of age. Revaccination by atomiser at 4 and 10 weeks of age. Where atomiser administration is impossible, revaccination by drinking water may be carried out.

Spray:

The product has been successfully used in most types of spray equipment; the droplet sizes varying from coarse (knapsack) to very fine (aerosol). Remove the aluminium seal from the vaccine vial. To dissolve the vaccine pellet, the rubber stopper should then be removed whilst the vial is immersed in a plastic measuring jug containing one litre (approximately 1 quart) of clean cool water. Half fill the vial with water, replace the stopper and shake to dissolve any remaining vaccine. Stir carefully to ensure even dispersal of vaccine. The vaccine concentrate should then
be added to the water in the sprayer tank and thoroughly mixed. Use deionised water or cold clean drinking water containing as little chlorine and as few metal ions as possible.
Vaccination should preferably be performed in the hatchery by hand spray, automatic spraying equipment or by eye/nose drop. Later vaccination should be given by an atomiser.
For spray administration, 250-500 mls of water per 1,000 chicks in the hatchery and 500 mls per 1,000 chicks on the farm is recommended.

Spray Method:

Hand spray and automatic spraying equipment (coarse drop spray):
- Spray the birds (the distance from the spraying head to the birds must be approximately 50 cm) and make sure all the birds get the vaccine directly.
- Use drops with a diameter of 0.12 – 0.15 mm.
- In warm weather, vaccination should preferably take place during the coolest part of the day.

Atomiser:

- Use the atomiser preferably in position 5 (drop size $\pm$0.05 mm).
- The birds should not be touched directly, but the area must be sprayed.
- Ensure that the ventilation is switched off and that air intakes and outlets are closed during vaccination and for twenty minutes afterwards.
- In warm weather, vaccination should preferably take place during the coolest part of the day.

After atomiser vaccination, intake of the vaccine by the birds is by inhalation. The air volume per bird in 30 minutes is independent of the number of birds per house (per m^3). Therefore the vaccine concentration in the air has to be

constant and independent of the number of birds per house volume (m^3). For a good immune response about 10 doses per m^3 (giving at least 10^7 EID_{50} per m^3) are required. This means that the number of doses needed has to be calculated on the size of the house expressed in m^3 and multiplied by 10.

Intranasal:

For use in birds from one day of age. Reconstitute the vaccine as directed below. Fit the drop dispenser on the bottle. Place finger over one nostril of the bird, allow one drop of the vaccine to fall into the other nostril. Vaccination is completed when the vaccine is inhaled into the nasal cavity. Do not release the bird until this occurs.

Eye Drop:

For use in birds from one day of age. Reconstitute the vaccine as directed below. Fit the drop dispenser on the bottle. Hold the bird so that one eye is pointed upwards and allow one drop of vaccine to fall into the eye. Birds should swallow during vaccination.

Reconstitution for intranasal and Eye Drop Routes:

Remove the aluminium foil and rubber stopper from the vaccine vial and add sterile water for injections to half fill the vial. Replace the rubber stopper and shake so that all the vaccine material is completely dissolved.

Dissolve the freeze-dried pellet in 30 ml sterile diluent for each 1000 doses. Shake gently until completely dissolved. The sterile water for injections should be at room temperature when used.

Drinking Water:

1. Make sure that all conduit pipes, tubing, troughs, drinkers etc are thoroughly clean and free of any trace of disinfectants, detergents, soap, etc.

2. Allow water to be consumed so that levels in drinkers are minimal before vaccine is applied. If water is still present, drain lines before applying vaccine. Apply vaccine over up to 3 hours, ensuring that all birds drink during this time. It may be necessary to withhold water on some sites prior to vaccination in order to ensure that all birds drink during the vaccination period.

3. Open the vaccine ampoule under water. Mix the contents of the vaccine ampoule with cold and fresh drinking water at the rate of 1,000 doses of the vaccine to 1 litre of water per day of age for 1,000 chickens. As the concentrated vaccine is slightly viscous, care should be taken to empty the ampoule and its top completely by rinsing them in water. Low-fat skimmed milk powder (ie <1% fat) may be added to the water (2 – 4 grams per litre) or skimmed milk (1 litre per 23 litres of water) to increase the stability of the virus. All tubing should be emptied of plain water, so

that the drinkers contain only vaccine water. Ideally vaccine should be administered in the volume of water consumed by the birds in up to 3 hours. If in doubt, measure water intake the day before administering vaccine.

4. Use the dissolved vaccine immediately following preparation.

5. Avoid exposure of the vaccine suspension to sunlight.

6. Water used for drinking administration of a live virus vaccine must be non-chlorinated and contain as few as possible metal ions.

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

No adverse reaction exceeding those discussed in section 4.6 was recorded following administration of an overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Newcastle Disease Virus.

ATCVet code: QI01AD06

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

D-mannitol
Gelatine
Inositol
NZ Case Plus

6.2 Incompatibilities

Do not mix with any other medicinal product except the live infectious bronchitis and Mareks disease vaccines in the Poulvac range by Zoetis.

6.3 Shelf life

24 months.

The reconstituted vaccine can be kept for 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

Size: 10 x 2,000, 10 x 5,000 or 10 x 10,000 dose vials.
Container: Type I hydrolytic glass vials.
Closures: Butyl rubber (PhEur) and aluminium tear-off cap.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4110

9. DATE OF FIRST AUTHORISATION

28 May 1995

10. DATE OF REVISION OF THE TEXT

August 2020

Approved: 14 August 2020