

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Poulvac IB Primer

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Avian infectious bronchitis vaccine (live), freeze-dried.

#### **Quantitative composition**

##### Active Ingredients

Infectious bronchitis virus strain H120

Infectious bronchitis virus strain D274 clone

##### Per dose

$10^{3.0} - 10^{5.4}$  EID<sub>50</sub>

$10^{3.0} - 10^{5.4}$  EID<sub>50</sub>

##### Excipients

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Oral solution *or* spray solution after reconstitution of the freeze-dried vaccine in water.

### **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 upper respiratory tract infections caused by strains of the Massachusetts serotype and Dutch variant strains D207/D274.

The onset of immunity is from 27 days post vaccination.

Protection of chicks will be of approximately 16 weeks duration at which age the chickens may be vaccinated with an appropriate inactivated IBV vaccine product.

#### **4.3 Contraindications**

Do not use in sick chickens.  
Refer to sections 4.4 and 4.7.

#### **4.4 Special warnings**

It is accepted that spray administration offers benefits over water administration in terms of ease of application and percentage of birds vaccinated. Nevertheless, greater secondary problems may result under certain management conditions. Spray vaccination should not be used if intercurrent infection is suspected. It is important to consult your veterinary adviser or Zoetis technical staff before using the spray technique.

Efficacy against infectious bronchitis caused by the 4/91 (793B) UK variant IB strain has not been demonstrated.

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, including special precautions to be taken by the person administering the medicinal product to animals**

i. Special precautions for use in animals

Care should be taken in the planning and implementation of vaccination programmes as vaccine virus may spread from vaccinates to non-vaccinated chickens. It is recommended that all chickens on a site be vaccinated with this product.

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

It is recommended to spray vaccinate in a sealed cabinet. Alternatively, the eyes and face of vaccination staff should be protected by a full facemask approved to BS2091 (e.g. a Siebe-Gorman vista type) and eye goggles should be worn. A helmet with filtered air circulation may be used instead of goggles and mask.

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

#### **4.6 Adverse reactions (frequency and seriousness)**

A mild vaccination reaction can be observed in the form of transient, slight respiratory symptoms such as occasional sneezing and coughing. No harmful clinical effects have been observed. Tracheal histopathology revealed very low scores in the post vaccination period.

#### **4.7 Use during pregnancy, lactation or lay**

Can be used before the onset of lay in chickens intended for breeding.

The safety of the veterinary medicinal product has been demonstrated when administered during lay.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Safety and efficacy data are available which demonstrate that this vaccine, when administered by the spray route to maternal antibody positive chicks, can be administered on the same day as Poulvac NDW and Poulvac SHS. 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 scheme:**

Broilers: vaccination from first day of life.

Future layers or breeders: vaccination from first day of life or during the 3rd to 4th week of life for immediate protection of young chickens and priming for subsequent vaccinations with an inactivated vaccine.

Layer or breeders: vaccination from onset of lay.

One dose per chicken to be administered with drinking water or by spray. The quantity of water to be used depends on the method of administration. Never use less than 1 dose per bird.

##### Drinking water

Discontinue any drinking water medication 24 hours before vaccination. Water containing a high level of free chlorine should not be used. A general indication is that if chlorine can be detected in the water by smell or taste it could deactivate the living virus.

If so, half a litre (1 pint) of skimmed milk should be thoroughly mixed into every 20 litres (5 gallons) of water or skimmed milk powder added at a rate of two grams per litre of water before adding vaccine.

Only perfectly clean and rust free utensils and drinkers (preferably plastic) should be used, and disinfectants must not be used for cleaning. Ensure that there is enough drinking trough space to allow all birds immediate access to the vaccine. No untreated water should be available until the treated water has been consumed.

Withhold drinking water for 2 hours before vaccination to stimulate thirst. 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 1 litre (approximately 1 quart) of clean cool water. Half fill the jug with water, replace the stopper and shake to dissolve any remaining vaccine.

The vaccine concentrate should then be added to and thoroughly mixed with sufficient drinking water to last for approximately 2 hours.

The approximate drinking water requirements for vaccination can be calculated from the age of the birds. Use as many litres of water as the age of the birds in days, per 1000 birds, up to a maximum of 40 litres per 1,000 birds.

Distribute the diluted vaccine evenly in the drinkers. Do not expose prepared drinking water vaccine to sunlight.

Return to regular watering only after the vaccine water has been consumed. The vaccine solution is best divided so that the drinkers are charged at least twice with vaccine to ensure a more widespread uptake.

If nipple drinkers are employed, ensure that header tanks are continually refilled with water containing vaccine.

The vaccine may be used in automatic watering equipment. However, the main supply should only be turned on when all the vaccine treated water has been consumed.

NB: Check that birds are never left without water after vaccine treatment.

### Spray

Poultvac IB primer has been used in most types of spray equipment. The equipment should provide a droplet size of 0.12 to 0.15 mm diameter. The distance from the spraying head to the bird must be approximately 50 cm. Use 0.15 to 0.5 litres of water per 1,000 birds depending upon the type of spray equipment to be used.

The vaccine should be dissolved as described under drinking water administration. The vaccine concentrate should then be added to the water in the sprayer tank and thoroughly mixed.

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

A ten-fold overdose administered by eye drop to day-old SPF chicks, observed over 21 days, elicited no effects more severe than those observed with a single dose.

#### **4.11 Withdrawal periods**

Zero days.

### **5. IMMUNOLOGICAL PROPERTIES**

To stimulate active immunity against infectious bronchitis virus, strain Massachusetts serotype and Dutch variant strains D207/D274.

ATCVet code: QI01AD07

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Mannitol  
Inositol  
NZ Case Plus  
Gelatin

#### **6.2 Incompatibilities**

Do not use with any other veterinary medicinal product.

#### **6.3 Shelf-life**

18 months.  
Reconstituted vaccine should be used within 4 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**

Nature: Type I glass (Ph.Eur) vial

Closure: Butyl rubber (Ph.Eur) and aluminium tear-off cap.

Content: Freeze-dried pellet.

Pack size: Pack of 10 vials containing 1,000, 2,000 or 5,000 doses.

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

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**

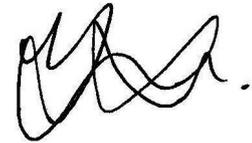
Vm 42058/4103

**9. DATE OF RENEWAL OF THE AUTHORISATION**

15 April 2005

**10. DATE OF REVISION OF THE TEXT**

August 2020

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Approved: 14 August 2020