

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTONBOARD BOX**  
**10x 1000 / 2500 / 5000 doses**

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

Poulvac IB Primer.  
Lyophilisate for suspension for spray, eye drop or drinking water administration for chickens.

**2. STATEMENT OF ACTIVE SUBSTANCES**

**Active substances:**

Live, attenuated avian Infectious Bronchitis Virus, strain H120:  $10^{3.0} - 10^{5.4}$   
EID<sub>50</sub>/ds  
Live, attenuated avian Infectious Bronchitis Virus, strain D274 Clone:  $10^{3.0} - 10^{5.4}$   
EID<sub>50</sub>/ds

**3. PHARMACEUTICAL FORM**

Lyophilisate for suspension.

**4. PACKAGE SIZE**

10 x 1000 doses  
10 x 2500 doses  
10 x 5000 doses

**5. TARGET SPECIES**

Chickens.

**6. INDICATION(S)**

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

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period(s): Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP

Once reconstituted use within 4 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**

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

**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**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 42058/5191

**17. MANUFACTURER'S BATCH NUMBER**

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Glass vials**  
**1000 / 2500 / 5000 doses**

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

Poulvac IB Primer.  
Lyophilisate for suspension for spray, eye drop or drinking water administration for chickens.

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Live, attenuated avian Infectious Bronchitis Virus, strain H120:  $10^{3.0} - 10^{5.4}$  EID<sub>50</sub>/ds  
Live, attenuated avian Infectious Bronchitis Virus, strain D274 Clone:  $10^{3.0} - 10^{5.4}$  EID<sub>50</sub>/ds

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

1000 doses  
2500 doses  
5000 doses

**4. ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**5. WITHDRAWAL PERIOD(S)**

Withdrawal period(s): Zero days.

**6. BATCH NUMBER**

Lot

**7. EXPIRY DATE**

EXP

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Poulvac IB Primer**  
**Lyophilisate for suspension for spray, eye drop or drinking water**  
**administration 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:

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

Manufacturer responsible for the batch release:

Zoetis Manufacturing & Research Spain, S.L.  
C/Campródon s/n "La Riba"  
17813 Vall de Bianya  
Girona  
Spain

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Poulvac IB Primer.  
Lyophilisate for suspension for spray, eye drop or drinking water administration for chickens.

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

One dose contains:

**Active substances:**

Live, attenuated avian Infectious Bronchitis Virus, strain H120:  $10^{3.0} - 10^{5.4}$   
EID<sub>50</sub>  
Live, attenuated avian Infectious Bronchitis Virus, strain D274 Clone:  $10^{3.0} - 10^{5.4}$   
EID<sub>50</sub>

Off-white to cream coloured lyophilisate.  
Upon reconstitution, transparent to white opaque suspension (depending on the volume of water used).

#### **4. INDICATION(S)**

For active immunisation of chickens against Massachusetts serotype strains and D274 like strains of Avian Infectious Bronchitis virus (IBV).

Onset of immunity: 27 days after vaccination

Duration of immunity: 16 weeks

#### **5. CONTRAINDICATIONS**

None.

#### **6. ADVERSE REACTIONS**

In very rare cases, a slight reaction to vaccination can be observed in the form of transient, mild respiratory symptoms.

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.

#### **7. TARGET SPECIES**

Chickens.

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

One dose of vaccine per bird administered by spray administration, eye drop administration or drinking water administration. The amount of water to be used depends on the method of administration:

For spray administration: Dilute and administer the reconstituted vaccine at a rate of one dose of reconstituted vaccine per bird, according to the directions of your specific coarse spray vaccination equipment. Recommended volume for one dose is between 0.1 and 0.5 ml.

The spray device used must be set to a droplet size of 0.12 to 0.15 mm in diameter. The distance from the spray head to the bird should be approximately 50 cm.

During spraying and for about 20 - 30 minutes thereafter, ventilation should be switched off or reduced. Dimming light sources is recommended to avoid unsettling the animals.

For eye drop administration: 50 ml per 1000 birds.

One drop (0.05 ml) of the vaccine solution is administered into an eye. In doing so, the head of the animal must be fixed so that the drop does not run down. 1000 doses of the vaccine are dissolved in 50 ml water.

For drinking water administration: Depending on the age of the birds: The amount of water in litres per 1000 chickens should be set according to the age of the chickens in days (up to a maximum of 40 litres).

Water containing a high level of chlorine or metal ions should not be used and conduit pipes, tubing, etc. should be thoroughly clean and free of traces of disinfectants and detergents. It is recommended to add protective proteins in the form of skimmed milk powder (2 g per litre of water) or skimmed milk (1 litre per 50 litres of water) to the water.

The birds should be deprived from water about 2 hours before vaccination. For vaccination, use as many litres of water as the age of the birds in days, per 1000 birds, up to a maximum of 40 litres as indicated above.

Prepare the amount of vaccine to be used within 2 hours. Remove the sealing cap and stopper from the vaccine vial and suspend the vaccine in the corresponding amount of water and mix carefully. Care should be taken to empty the ampoule completely and administer the diluted vaccine immediately. Make sure that birds do not have access to untreated water until the treated water has been consumed.

#### **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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

One day before and after vaccination no drugs or disinfectants should be applied to the chickens.

## **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.

Do not use this veterinary medicinal product after the expiry date stated on the label.

Shelf life after reconstitution according to directions: 4 hours.

## 12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals:

The vaccine strain may spread to unvaccinated chickens. Safety and reversion to virulence trials have shown that vaccine strain is safe for chickens. 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:

Personal protective equipment consisting of goggles and dust masks or a helmet with filtered air circulation should be worn when handling the veterinary medicinal product especially while vaccination according to the spraying method.

Personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots).

Lay:

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

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this vaccine can be administered from day of age onwards by course spray and eyedrop before administration of Poulvac IB QX (where authorised) with a 7 to 14 day interval between both administrations. For the associated use, the onset of immunity is 21 days after the Poulvac IB QX vaccination for the claimed protection against QX-like IBV strain and the onset of immunity is 27 days against Massachusetts serotype and D274-like strains of IBV after the Poulvac IB Primer vaccination. An onset of immunity of 21 days after the second vaccination against IBV Variant 2 (IS-1494-like) and 793B serotype strains has also been established for the associated use, with Poulvac IB QX as detailed above, as demonstrated by a reduction of respiratory signs caused by Variant 2 (IS-1494-like) and 793B serotype strains of IBV (as assessed by the ciliary activity of tracheal explants). The possible interference of MDAs on efficacy against Variant 2 and 793B serotype strains was not investigated. The safety parameters and adverse reactions are not different from those described for the vaccines administered separately.

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.

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

Overdose (symptoms, emergency procedures, antidotes):

Administration of a 10-fold overdose does not result in symptoms different from those mentioned under section 6.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

### **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. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **15. OTHER INFORMATION**

The vaccine is supplied in boxes of ten vials of 1000, 2500 or 5000 doses.

Not all pack sizes may be marketed.

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

*Gavin Hall*  
Approved: 10 July 2025