ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Poulvac IB Primer – Outer Label
10x 1000 dose
10x 2000 dose
10x 5000 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB Primer

2. STATEMENT OF ACTIVE SUBSTANCES

Live infectious bronchitis disease vaccine containing strains D274 and H120 $10^{3.0}$ – $10^{5.4}$ EID_{50} per dose.

3. PHARMACEUTICAL FORM

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

4. PACKAGE SIZE

10 x 1,000 dose vials
10 x 2,000 dose vials
10 x 5,000 dose vials

5. TARGET SPECIES

For chickens from one day of age

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

For drinking water or spray administration.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNINGS, IF NECESSARY

For use see package leaflet.

10. EXPIRY DATE

EXP:
Reconstituted vaccine should be used within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2°C – 8°C)
Do not freeze. Protect from light.

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

For use see package leaflet.

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

FOR ANIMAL TREATMENT ONLY

POM-V
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the 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

Vm 42058/4103

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Poulvac IB Primer – Vial Label
1000 dose
2000 dose
5000 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB Primer

2. QUANTITY OF THE ACTIVE SUBSTANCES

Live infectious bronchitis disease vaccine.
Containing strains D274 and H120.

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

1,000 doses
2,000 doses
5,000 doses

4. ROUTE OF ADMINISTRATION

For drinking water or spray administration.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Reconstituted vaccine should be used within 4 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY.

For use – see leaflet.
Store and transport refrigerated (2°C – 8°C)
Do not freeze. Protect from light.
POM-V
Vm 42058/4103
Zoetis UK Limited, Surrey

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Poulvac IB Primer

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 batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodon s/n "la Riba"
17813 Vall de Bianya (Girona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB Primer

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

A freeze-dried pellet or powder containing live infectious bronchitis vaccine virus strains H120, $10^{3.0}$ – $10^{5.4}$ EID_{50} and D274 clone, $10^{3.0}$ – $10^{5.4}$ EID_{50} per dose.

4. INDICATIONS

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.

5. CONTRAINDICATIONS

Do not use in sick chickens.

6. ADVERSE REACTIONS

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.

7. TARGET SPECIES

Chickens from one day of age.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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 vial 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
Poulvac 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.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport refrigerated (2°C – 8°C).
Do not freeze. Keep the container in the outer carton. Protect from light.
Reconstituted vaccine should be used within 4 hours.

12. SPECIAL WARNINGS

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.
The safety of the medicinal product has been demonstrated when administered during lay.
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.
Do not use with any other veterinary medicinal product.
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.
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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

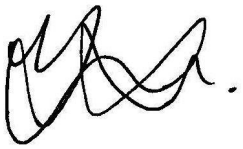
Following vaccination of susceptible chicks, immunity lasts up to approximately 3 to 4 months.
Thereafter vaccination using other vaccine based on M41 or D207/D274 strains may be advisable.
In any animal population there will be a small number of individuals which fail to respond fully to vaccination.
Successful vaccination depends upon correct storage and administration of vaccine and the animals' ability to respond.
Immune competence can be influenced by genetic factors, intercurrent infection, age, nutritional status, concurrent drug therapy, stress etc.

For Animal Treatment Only

LEGAL CATEGORY
POM-V
Prescription Only Medicine – Veterinarian
To be supplied only on veterinary prescription.

PACKAGE QUANTITIES
1,000 and 5,000 dose vials, in protective outer packaging containing 10 vials.
Not all pack sizes may be marketed.

MARKETING AUTHORISATION NUMBER
Vm 42058/4103



Approved: 14 August 2020