# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box of one or ten glass vials of 1,000 or 2,500 or 5,000 or 10,000 doses**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB H120 lyophilisate for suspension for oculonasal use, ocular use or use in drinking water.

## 2. STATEMENT OF ACTIVE SUBSTANCES

Live attenuated avian infectious bronchitis virus, strain H120: $10^{3.0} – 10^{4.9}$ $EID_{50}$/dose*.
*$EID_{50}$ = 50% embryo infective dose.

## 3. PACKAGE SIZE

1 x 1,000 doses
10 x 1,000 doses
1 x 2,500 doses
10 x 2,500 doses
1 x 5,000 doses
10 x 5,000 doses
1 x 10,000 doses
10 x 10,000 doses

## 4. TARGET SPECIES

Chickens.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Spraying, eye drops or use in drinking water.

## 7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 4 hours.

## 9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

## 10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

## 11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

## 12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

## 14. MARKETING AUTHORISATION NUMBERS

Vm 60021/3068

## 15. BATCH NUMBER

Lot {number}

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

**Glass vial with 1,000, 2,500, 5,000 and 10,000 doses**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB H120

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Live attenuated avian Infectious Bronchitis Virus, strain H120: $10^{3.0}$ – $10^{4.9}$ $EID_{50}$/dose

1,000 doses
2,500 doses
5,000 doses
10,000 doses

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Poulvac IB H120 lyophilisate for suspension for oculonasal use, ocular use or use in drinking water for chickens

## 2. Composition

Each dose contains:

**Active substance:**

Live attenuated avian infectious bronchitis virus, strain H120: $10^{3.0}$ – $10^{4.9}$ $EID_{50}$*.
*$EID_{50}$ = 50% embryo infective dose.

Off-white to cream coloured lyophilisate.

## 3. Target species

Chickens.

## 4. Indications for use

For the active immunisation of chickens (broilers, future layers or breeders) in order to reduce the detrimental effect on the ciliary activity resulting from infection with infectious bronchitis virus (IBV) Massachusetts serotype strains, which is related to the development of respiratory clinical signs.

Onset of immunity: 25 days after vaccination.
Duration of immunity: 16 weeks.

## 5. Contraindications

None.

## 6. Special warnings

Special warnings:
Vaccinate healthy animals only.
Maternally derived antibodies (MDAs) 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.

Special precautions for safe use in the target species:
The vaccine strain can spread from vaccinated to non-vaccinated chickens. Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated 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).

Laying birds:
The safety of the veterinary medicinal 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.

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 decided on a case by case basis.

Overdose:
Administration of a 10-fold overdose does not result in symptoms different from those mentioned under section “Adverse events”.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

## 7. Adverse events

Chickens:

| Very rare (<1 animal / 10,000 animals treated, including isolated reports): |
|---|
| Respiratory signs[1] |

[1]Generally mild and transient in nature.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

## 8. Dosage for each species, routes and method of administration

For chickens from one day of age.
One dose per chicken to be administered by coarse spray, by eye drop or with drinking water. The quantity of water to be used depends on the method of administration. Never use less than 1 dose per chicken.

## 9. Advice on correct administration

*For spray administration (oculonasal use):*
The product can be used in most types of spray equipment. The equipment should provide coarse spray (droplets between 80 to 160 µm). The distance from the spraying head to the bird must be approximately 50 cm. 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. It is recommended to use 0.15 to 0.5 litres of water per 1,000 birds depending of the type of spray equipment to be used.
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 (ocular use):*
Use 30 to 50 ml of deionized water per 1,000 doses (birds) depending on the type of eye-dropper to be used. One drop equal to one dose (0.03 to 0.05 ml depending on the reconstituted volume) of the vaccine solution is administered into one eye per chicken. The deionised water should be at room temperature when used. Hold the chicken so that one eye is pointing upwards and allow one drop of vaccine to fall into the eye. Chickens should swallow during vaccination.

*For drinking water administration (use in 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 of skimmed milk should be thoroughly mixed into every 20 litres 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) free of any trace of disinfectants, detergents, soap, etc. should be used. Ensure that there is enough drinking trough space to allow all chickens immediate access to the vaccine. No untreated water should be made 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 chickens. Use as many litres of water as the age of the chickens in days, per 1,000 chickens, up to a maximum of 40 litres per 1,000 chickens.
Distribute the diluted vaccine evenly in the drinkers. Do not expose prepared drinking water vaccine to sunlight.
The vaccine suspension 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. Return to regular watering only after the vaccine water has been consumed.

Upon reconstitution, transparent to white opaque suspension (depending on the volume of diluent used).

## 10. Withdrawal periods

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 which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: 4 hours.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

Vm 60021/3068

The vaccine is supplied in quantities of 1,000, 2,500, 5,000 or 10,000 doses per vial in cardboard boxes of 1 or 10 vials.

Not all pack sizes may be marketed.

## 15. 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.

## 16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

## 17. Other information

This vaccine is intended to stimulate active immunity against Massachusetts strains of infectious bronchitis virus (IBV).

POM-V

Approved 24 April 2025
Gavin Hall