

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

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**BOX OF 10 VIALS, EACH CONTAINING 5,000 OR 10,000 DOSES**

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

Poulvac IBMM + ARK lyophilisate for oculonasal suspension.

**2. STATEMENT OF ACTIVE SUBSTANCES**

Live avian infectious bronchitis virus (Massachusetts 1263 and Arkansas 3168 strains):  $10^{3.3}$  -  $10^{5.8}$  EID<sub>50</sub>/dose

**3. PACKAGE SIZE**

10 x 5,000 doses  
10 x 10,000 doses

**4. TARGET SPECIES**

Chickens (broilers).

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Spraying.

**7. WITHDRAWAL PERIODS**

Withdrawal period: Zero days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}  
Once reconstituted use within 2 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Do not freeze.  
Protect from light.

**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 60021/3094

**15. BATCH NUMBER**

Lot {number}

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

**GLASS VIAL WITH 5,000 OR 10,000 DOSES**

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

Poulvac IBMM + ARK

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Live avian Infectious Bronchitis Virus (Massachusetts and Arkansas strains):  $10^{3.3} - 10^{5.8}$  EID<sub>50</sub>/dose

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 IBMM + ARK lyophilisate for ocularnasal suspension for chickens

### 2. Composition

Each dose contains:

#### Active substances:

Live avian infectious bronchitis virus (strain Massachusetts1263 and strain Arkansas 3168)  $10^{3.3} - 10^{5.8} \text{EID}_{50}^*$   
\*EID<sub>50</sub>: Embryo infective dose 50%.

Off-white to cream coloured lyophilisate.

### 3. Target species

Chickens (broilers).

### 4. Indications for use

For the active immunisation of broilers to reduce the severity of upper respiratory tract infections caused by Massachusetts and 793/B/91-type strains of avian infectious bronchitis virus.

Onset of immunity: 21 days after vaccination.

Duration of immunity: 6 weeks after vaccination.

Protection has also been demonstrated in the presence of maternally derived antibodies.

### 5. Contraindications

None.

### 6. Special warnings

#### Special warnings:

Vaccinate healthy animals only.

#### Special precautions for safe use in the target species:

The vaccine should not be used if an intercurrent infection is suspected.

The vaccine should not be used at sites where both broilers and breeders are kept.

Chickens should not be re-vaccinated.

The vaccine should only be used after it has been established that 793/B/91 like avian infectious bronchitis virus serotypes are epidemiologically relevant. The vaccine strains can spread to in contact birds for up to 30 days after vaccination. Special precautions should be taken to avoid spreading of the vaccine strain to pheasants.

It is recommended to vaccinate all chickens on a site with this product.

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

Personal protective equipment consisting of goggles and dust mask or a helmet with filtered air circulation should be worn when handling the veterinary medicinal product.

Laying birds:

Do not use in birds intended for laying or breeding.

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 made on a case by case basis.

Overdose:

Administration of a 10-fold overdose does not result in symptoms different from those mentioned in section "Adverse events".

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

## **7. Adverse events**

Chickens (broilers):

Common (1 to 10 animals / 100 animals treated):
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Respiratory signs (including gasping, snicking and raling) <sup>1</sup>
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<sup>1</sup>Generally mild; may be observed for approximately three days.

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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

One dose of vaccine per bird by spray administration (oculonasal use) from one day of age.

## **9. Advice on correct administration**

This vaccine has been used in most types of spray equipment handsprayers (e.g. ASL Polyspray 2), knapsack sprayers (e.g. Birchmeyer with 0.55 or 1.6 mm spray nozzle, Gloria with 1.0 mm nozzle) or automatic spraying equipment (e.g. Bimex). The apparatus should be set to deliver a coarse spray (droplet size of 80-160 micrometres), allowing a dose of 0.5 ml per bird.

The lyophilised vaccine should be reconstituted with water of good quality at room temperature e.g. deionised water or good quality drinking water.

The lyophilised vaccine should be reconstituted as follows:

Remove the aluminium cap from the vial. To reconstitute the lyophilised vaccine, the rubber stopper should be removed whilst the vial is immersed in a plastic measuring jug containing 0.5 litre of clean cool water.

Half fill the vial with water, replace the stopper and shake to remove any remnants in the vial.

The content of the vial should then be added to the water in the jug, mixed well and transferred to the sprayer tank and thoroughly mixed. For the 5,000 dose vial a total amount of 2.5 l water is required and for the 10,000 dose vial a total amount of 5 l water should be used.

The chickens should be sprayed in chick boxes or brooding rings in the house to avoid loss of vaccine virus.

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

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month. Shelf life after reconstitution according to directions: 2 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 60021/3094

The vaccine is supplied in quantities of 5,000 or 10,000 doses per vial in boxes of 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](http://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

<Local representatives <and contact details to report suspected adverse reactions>:>  
*To be completed nationally (if applicable).*

#### **17. Other information**

This vaccine is intended to stimulate active immunity against avian infectious bronchitis virus, strains Massachusetts type and 793/B/91 like (Arkansas).

*Gavin Hall*  
Approved: 26 June 2025