# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

POULVAC IBMM + ARK
Lyophilisate for suspension for spray administration for chickens.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose contains:

**Active Substances:**
Live avian infectious bronchitis virus $10^{3.3} - 10^{5.8}$ $EID_{50}$*
(Strain Massachusetts1263 and Strain Arkansas 3168)
*$EID_{50}$: Embryo infective dose 50%

**Excipients:**
For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

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

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Chickens (broilers).

### 4.2 Indications for use, specifying the target species

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.

### 4.3 Contraindications

None.

## 4.4 Special warnings for each target species

Vaccinate healthy animals only.

## 4.5 Special precautions for use

Special precautions for use in animals
Do not re-vaccinate birds.
Spray vaccination should not be used if an intercurrent infection is suspected.
Avian infectious bronchitis virus strains Massachusetts and Arkansas may spread to in contact birds. The duration of spreading of the vaccine virus is for up to 30 days following vaccination.
It is recommended that all chickens on a site be vaccinated with this product.
Do not use on mixed sites of broilers and breeders.

The product should only be used where it has been established that 793/B/91 like avian infectious bronchitis virus serotypes are epidemiologically relevant in the area.
Special precautions should be taken to avoid spread of the vaccine virus from vaccinates to pheasants

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.

## 4.6 Adverse reactions (frequency and seriousness)

Commonly a slight transient respiratory reaction, including gasping, snicking and raling, may be observed for approximately three days.

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).

## 4.7 Use during pregnancy, lactation or lay

Do not use in birds intended for laying or breeding.

## 4.8 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

## 4.9 Amounts to be administered and administration route

Coarse spray vaccination from one day of age.
Coarse spray:
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.

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

Administration of a 10-fold overdose does not result in symptoms different from those mentioned in section 4.6.

## 4.11 Withdrawal period(s)

Zero days.

# 5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Aves, live viral vaccines for domestic fowl.
ATCvet code: QI01AD07.

To stimulate active immunity against avian infectious bronchitis virus, strains Massachusetts type and 793/B/91 like (Arkansas).

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Mannitol
Inositol
Gelatin
N-Z Case Plus

### 6.2 Major incompatibilities

Do not mix with any other medicinal product.

### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after reconstitution according to directions: 2 hours

### 6.4 Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

Hydrolytic type I glass vials with a butyl rubber (Ph Eur) stopper and aluminium cap.

10 ml glass vial containing 5,000 doses (box of 10 vials)
20 ml glass vial containing 10,000 doses (box of 10 vials)

Not all pack sizes may be marketed.

### 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER

Vm 42058/4104

## 9. DATE OF FIRST AUTHORISATION

25 January 2001

## 10. DATE OF REVISION OF THE TEXT

March 2022

Approved 09 March 2022