SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IBMM + ARK lyophilisate for oculonasal suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active Substances:

Live avian infectious bronchitis virus (strain Massachusetts1263 and strain Arkansas 3168) $10^{3.3}$ – $10^{5.8}$ EID_{50}*

*EID_{50}: Embryo infective dose 50%.

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Off-white to cream coloured lyophilisate.

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
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.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Chickens (broilers):

Common (1 to 10 animals / 100 animals treated):	Respiratory signs (including gasping, snicking and raling)[1]

[1]Generally mild; may be observed for approximately three days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

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 made on a case by case basis.

4.9 Amount(s) to be administered and administration route

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

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).

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

This vaccine is intended 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 veterinary 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).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Hydrolytic type I glass vials closed with butyl rubber stopper and sealed with an aluminium crimp cap.

Pack sizes:
Box of 10 x 5,000 doses.
Box of 10 x 10,000 doses.

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

Medicines should not be disposed of via wastewater.

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 42058/5140

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25 January 2001

10. DATE OF REVISION OF THE TEXT

March 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved: 27 September 2024