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 suspension for spray administration for chickens.

2. STATEMENT OF ACTIVE SUBSTANCES

Live avian infectious bronchitis virus (Massachusetts 1263 and Arkansas 3168 strains): $10^{3.3}$ -$10^{5.8}$ EID_{50}/ds

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for spray administration.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens (broilers).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

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

For animal treatment only.

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

Keep out of the sight and 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(S)

Vm 42058/4104

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10/20 ml glass vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live avian infectious bronchitis virus (Massachusetts and Arkansas strains): $10^{3.3}$-$10^{5.8}$ EID_{50} /ds

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

5,000 doses
10,000 doses

4. ROUTE(S) OF ADMINISTRATION

Read Package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
POULVAC IBMM + ARK
Lyophilisate for suspension for spray administration for chickens.

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 the batch release:
Zoetis Manufacturing & Research Spain, S.L
C/Camprodon s/n "La Riba"
17813 Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

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%

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

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A slight transient respiratory reaction, including gasping, snicking and raling, is commonly 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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (broilers).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

One dose of vaccine per bird administered by coarse spray from one day of age.

9. ADVICE ON CORRECT ADMINISTRATION

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 vaccine 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.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC – 8 ºC).
Protect from light. Do not freeze
Do not use this veterinary medicinal product after the expiry date stated on the label/carton.
Shelf life after reconstitution according to directions: 2 hours

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals:
Do not re-vaccinate birds.
Spray vaccination should not be used if an intercurrent infection is suspected.
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 spreading of the vaccine virus from vaccinates to pheasants.
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.

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.

Lay:
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 decided on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):
Administration of a 10-fold overdose does not result in symptoms different from those mentioned in section adverse reactions.

Incompatibilities:
Do not mix with any other medicinal product.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2022

15. OTHER INFORMATION

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

Approved 09 March 2022