ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX OF ONE VIAL OR TEN VIALS OF 2000, 5000 OR 10000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB QX lyophilisate for oculonasal suspension.

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Live attenuated Avian Infectious Bronchitis Virus, strain L1148 $10^{3.0}$ – $10^{5.0}$ EID_{50}*.
*EID_{50} = 50% Embryo Infective Dose.

3. PACKAGE SIZE

1 x 2000 doses
1 x 5000 doses
1 x 10000 doses
10 x 2000 doses
10 x 5000 doses
10 x 10000 doses

4. TARGET SPECIES

Chickens.

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

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/3005

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL 1 X OR 10 X 2000, 5000, 10000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB QX

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Live attenuated Avian Infectious Bronchitis Virus, strain L1148 $10^{3.0}$ –$10^{5.0}$ EID_{50}/dose
2000 doses
5000 doses
10000 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 QX lyophilisate for oculonasal suspension for chickens

2. Composition

Each dose contains:

Active substance:
Live attenuated Avian Infectious Bronchitis Virus, strain L1148 $10^{3.0}$ –$10^{5.0}$ EID_{50}*.
*EID_{50} = 50% Embryo Infective Dose.

Off-white, beige coloured lyophilisate.

3. Target species

Chickens.

4. Indications for use

For active immunisation of chickens in order to reduce respiratory signs of Infectious Bronchitis caused by QX-like variants of Infectious Bronchitis virus.

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 63 days after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
The vaccine virus is capable of spreading to in contact birds for a minimum of 14 days after vaccination, and appropriate care should be taken to separate vaccinated from non-vaccinated chickens. Precautionary measures should be taken to prevent spreading to wildlife. Cleaning and disinfection of the premises after vaccination is advisable.

This vaccine should only be used after it has been established that the QX-like variant strain is epidemiologically relevant.

It is important to avoid introduction of the IB QX vaccine virus into premises in which the wild type strain is not present. The IB QX vaccine should only be applied in

hatcheries if adequate controls are in place to avoid the spread of the vaccine virus to birds that will be transported to non-IB QX exposed flocks.

The vaccine has been demonstrated to provide protection against QX-like variant. The protection against other circulating IB strains has not been investigated.

As there is a small range between the efficacious vaccine dose and a non-efficacious dose, take care to administer the right dose.

Vaccinate healthy animals only.

Special precautions for safe use in the target species:
All chickens on the site should be vaccinated at the same time.
When vaccination is planned in future layers or breeders younger than 7 days, the parent flock should be vaccinated with an IB vaccine to ensure progeny with MDAs against IBV.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken when reconstituting and administering the vaccine. Wear a suitable respiratory mask and eye protection to avoid direct contact with the aerosolized vaccine. Wash and disinfect hands after use.

Laying birds:
The safety of the veterinary medicinal product has been demonstrated when administered during lay. The efficacy of the veterinary medicinal product has not been demonstrated when administered during lay.
A decision to use this vaccine during lay should be made on a case by case basis.

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:
Renal lesions (paleness, microscopic lesions) can be observed after administration of a 10-fold overdose.

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 last a few 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.

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

Broilers: one dose of vaccine from 1 day of age by spray vaccination.
Future layers or breeders: one dose of vaccine from 7 days of age by spray vaccination. The vaccine may be administered as early as 1 day of age to future layers or breeders with MDAs against IBV.

9. Advice on correct administration

The veterinary medicinal product can be used in most types of spray equipment. The equipment should provide coarse spray (droplets greater than 100 µm). The distance from the spraying head to the bird is dependent upon the type of sprayer used. It is recommended to consult the instructions from the manufacturer of the spraying device before use. Resuspension volumes vary based upon the type of spray equipment as well. The recommended resuspension volume for 1 dose is between 0.15 and 0.5 ml.
Remove the aluminium seal from the vaccine vial. To dissolve the vaccine pellet, the rubber stopper should be removed whilst the vial is immersed in a plastic measuring jug containing 1 litre 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 the water in the spray tank and thoroughly mixed. Administer at a rate of one dose of prepared vaccine per bird.

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.

Keep the vial in the outer carton in order to protect it from light.
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze. Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial 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 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

Box of one vial or ten vials of 2000, 5000 or 10000 doses.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

February 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

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:

17. Other information

Active immunisation against avian Infectious Bronchitis virus variant strain IB QX-like which causes infectious bronchitis in chickens.

Approval 21 April 2023