1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB QX lyophilisate for oculonasal suspension for chickens

2. QUALITATIVE AND QUANTITATIVE 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.

Excipients:

Qualitative composition of excipients and other constituents
D-mannitol
Gelatine
Myo-Inositol
Peptone
Water for injection

Off-white, beige coloured lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

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.

3.3 Contraindications

None.

3.4 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 IBV 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered by coarse spray after administration of Poulvac IB Primer (where authorised) from day of age onwards by coarse spray and eyedrop with a 7 to 14 day interval between both administrations. For the associated use, the onset of immunity is 21 days after the Poulvac IB QX vaccination for the claimed protection

against QX-like IBV strain and the onset of immunity is 27 days against Massachusetts serotype and D274-like strains of IBV after the Poulvac IB Primer vaccination. An onset of immunity of 21 days after the second vaccination against IBV Variant 2 (IS-1494-like) and 793B serotype strains has also been established for the associated use, with Poulvac IB Primer as detailed above, as demonstrated by a reduction of respiratory signs caused by Variant 2 (IS-1494-like) and 793B serotype strains of IBV (as assessed by the ciliary activity of tracheal explants). The possible interference of MDAs on efficacy against Variant 2 and 793B serotype strains was not investigated. The safety parameters and adverse events are not different from those described for the vaccines administered separately.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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.

3.9 Administration routes and dosage

Vaccination schedule
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.

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).

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : QI01AD07.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Glass vial closed with chlorobutyl rubber stopper and sealed with an aluminium crimp cap.

Pack sizes:
Box of 1 x 2000 doses
Box of 1 x 5000 doses
Box of 1 x 10 000 doses
Box of 10 x 2000 doses
Box of 10 x 5000 doses
Box of 10 x 10 000 doses

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/051/001

8. DATE OF FIRST AUTHORISATION

06/09/2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

15/11/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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