1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IB QX lyophilisate for oculonasal suspension/use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Avian infectious bronchitis virus, type QX, strain 1285, Live: $10^{3.7} – 10^{5.3}$ EID_{50}*

* EID_{50} = 50% embryo infective dose (virus titre required to produce infection in 50 % of the embryos inoculated)

Excipients:

Qualitative composition of excipients and other constituents
Povidone K 25
Bacto-peptone
Monosodium glutamate
Potassium dihydrogen phosphate
Potassium hydroxide
Dextran 40 000

Cream to yellow coloured lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For the active immunisation of chickens (broilers, future layers and future breeders) in order to reduce respiratory signs of avian infectious bronchitis caused by QX-like variants of infectious bronchitis virus (IBV).

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 10 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

All birds in the flock should be vaccinated at the same time.

Vaccinated chickens may excrete the vaccine strain for a minimum of 28 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided.

Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.

Avishield IB QX is intended to protect chickens against respiratory signs of disease caused by IBV QX-like strains only and should not be used as a replacement for other IBV vaccines. Care should be taken to avoid the introduction of the vaccine strain into an area where it is not present.

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. Wash and disinfect hands and equipment after administration of the vaccine to prevent the spread of the virus. When spraying the vaccine, personal protective equipment consisting of a mask with eye protection should be worn by the operator and staff.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Common (1 to 10 animals / 100 animals treated):	Sneezing.*

* During the first week after vaccination. If it occurs, it resolves spontaneously and does not need treatment.

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 national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

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 mixed and administered with vaccines Avishield IB H120 and Avishield IB GI-13 by spray application. Read the product information of those two vaccines before use.
The safety parameters of the mixed vaccines are not different from those described for the vaccines administered separately.
For the mixed products the onset of immunity is 3 weeks, and the duration of immunity is 8 weeks for Avishield IB H120 and Avishield IB GI-13; and 10 weeks for Avishield IB QX.

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

Coarse spray or oculonasal use: from one day of age.
In drinking water use: from 7 days of age.

Administer one dose per animal by either coarse spray, oculonasal or in drinking water use. Where the number of chickens is between the standard dosages, the next higher dosage should be used.
After reconstitution the vaccine appears as a clear to slightly opalescent suspension.

1. Coarse spray
It is recommended to reconstitute 1000 doses of the vaccine in 150 - 300 ml of distilled water. The number of doses to be used corresponds to the number of birds in the flock.
The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds, and will vary according to the age of the birds being vaccinated and the management system, however at least 150 – 300 ml of water per 1000 doses is suggested.
The reconstituted vaccine suspension should be spread evenly over the correct number of chickens, at a distance of 30 – 40 cm using a coarse spray (targeted average droplet size of 150 - 170 micrometers), preferably when the chickens are sitting together in dim light. The spray apparatus should be free from sediments, corrosion and traces of disinfectants and ideally should be used for vaccination purposes only. During and after vaccination ventilation should be switched off in order to avoid turbulences.

When mixing this product with Avishield IB H120 and Avishield IB GI-13, use the same total volume of water as for a single application. For example, 1000 doses of Avishield IB QX, 1000 doses of Avishield IB H120, and 1000 doses of Avishield IB GI-13 should be reconstituted in a total of 150-300 ml of water.

2. In drinking water use
Reconstitute the vaccine in cool and clean water without traces of chlorine, other disinfectants or impurities in a number of doses corresponding to the number of birds to be vaccinated.
The vaccine should be reconstituted immediately before use.

The volume of water for reconstitution depends on the age of the birds, the breed, the management practice and weather conditions.
In order to determine the quantity of water in which the vaccine will be reconstituted for the vaccination of chickens in a younger age category (until third week of life), the following guideline applies:

- multiplying the number of birds in the thousands with the day of life (e.g. 1 thousand of chickens in the 7th day of life = 1 x 7 = 7 L).

It is important to reconstitute the vaccine in an amount of water which will be drunk within 1.5 - 2.5 hours (taking into account the different types of drinking systems for poultry).
In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to vaccination (depending on the air temperature).
Always make sure that there is food available when vaccinating. Birds will not drink if they have no food to eat. The drinking system should be clean, without traces of chlorine, other disinfectants or impurities.

3. Oculonasal use
Reconstitute 1000 doses of the vaccine in 100 ml distilled water.
A dose of reconstituted vaccine is 0.1 ml, i.e. two drops of a standardised dropper (of which the droplet size is known and consistent), irrespective of poultry age, weight and type. Instil one drop

(0.05 ml) into an eye and one drop (0.05 ml) into a nostril. Ensure that the nasal drop is inhaled before releasing the bird.

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

After the administration of a 10 fold overdose, no adverse reactions other than one described in section Adverse events was observed.

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

To stimulate active immunity in chickens against QX-like strains of avian infectious bronchitis virus (vaccinal strain QX 1285 belongs to D388 serotype/GI-19 lineage).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except those mentioned in section 3.8 above.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after reconstitution according to directions: 3 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

The vaccine is filled into colourless glass vials (type I), which are closed with bromobutyl rubber stoppers and sealed with aluminium caps.

Pack sizes:
Cardboard box with 10 vials of 1000 doses of vaccine.
Cardboard box with 10 vials of 2500 doses of vaccine.
Cardboard box with 10 vials of 5000 doses of vaccine.

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

Genera d.d.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10405/007/001

8. DATE OF FIRST AUTHORISATION

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

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*).