ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box with 10 vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:
Avian infectious bronchitis virus, type QX, strain 1285, Live: $10^{3.7}$ – $10^{5.3}$ EID_{50}

3. PACKAGE SIZE

10 x 1000 doses
10 x 2500 doses
10 x 5000 doses

4. TARGET SPECIES

Chickens (broilers, future layers and future breeders).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oculonasal, spray or in drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 3 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

IZO S.r.l a socio unico

14. MARKETING AUTHORISATION NUMBER

Vm 61812/3003

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Glass vials with 1000, 2500 or 5000 doses of vaccine}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IB QX

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose contains:
Avian infectious bronchitis virus, type QX, strain 1285, Live: $10^{3.7}$ – $10^{5.3}$ EID_{50}

1000 doses.
2500 doses.
5000 doses.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 3 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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)

Cream to yellow coloured lyophilisate.

3. Target species

Chickens.

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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 strain only and should not be used as a replacement for other IBV vaccines. Care should be taken to avoid the introduction of the QX 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.

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

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.

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

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except those mentioned in the section “Interaction with other medicinal products and other forms of interaction” above.

7. 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 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 its local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

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.

9. Advice on correct administration

After reconstitution the vaccine appears as a clear to slightly opalescent suspension.

1. Coarse spray
It is recommended to reconstitue 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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 3 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 or pharmacist 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

Vm 61812/3003

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
IZO S.r.l. a socio unico
Via San Zeno 99/A
25124 Brescia
Italy
Tel. +39 030 2420583
Email: farmacovigilanza@izo.it

Manufacturer responsible for batch release:
Genera d.d.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

17. Other information

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

Gavin Hall
Approved: 08 June 2026