1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IB GI-13 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 793/B, strain V-173/11, Live $10^{2.7}$ - $10^{4.6}$ EID_{50}*

* EID_{50} = 50% Embryo infective dose.

Excipients:

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

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 in order to reduce the detrimental effect on the ciliary activity resulting from infection by avian infectious bronchitis virus, serotype 793B (GI-13 lineage), which may be manifested in respiratory clinical signs.

Onset of immunity: 10 days after vaccination.
Duration of immunity: 8 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Maternally derived antibodies (MDA) can interfere with the development of active immunity. Chickens can be vaccinated in the presence of MDA: immunity in chickens with MDA will be developed 21 days after vaccination.

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.
The vaccine strain is excreted from respiratory and intestinal tract. Appropriate measures should be taken to prevent contact between vaccinated and non-vaccinated animals. Measures should be taken to prevent spread to wild animals. Housing should be cleaned and disinfected after each production cycle.
Vaccinated chickens may excrete the vaccine strain for a minimum of 28 days following vaccination and the vaccine strain can spread to susceptible, unvaccinated chickens. During this time, the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided. It is also possible for the vaccine strain to spread to non-target susceptible species.

Avishield IB GI-13 is intended to protect chickens against respiratory signs of disease caused by IBV variant 793B serotype (GI-13 lineage) strain only and should not be used as a replacement for other IBV vaccines. Care should be taken to avoid the introduction of the variant 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. When spraying the vaccine, personal protective equipment consisting of a mask with eye protection should be worn when handling the veterinary medicinal product.

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

3.6 Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Respiratory sound[1]

[1] Tracheal rales for 1-13 days after oculonasal vaccination. Resolves spontaneously without 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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
The safety of the vaccine has been demonstrated when administered during lay.

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 Avishield IB H120 or with both Avishield IB H120 and Avishield IB QX by coarse spray from one day of age onwards. Read the product information of Avishield IB H120 and Avishield IB QX before use.

The safety parameters of the mixed vaccines are not different from those described for the vaccines administered separately. The safety of the mixed vaccines has not been investigated when administered during lay.

<table>
<tr><td colspan="3">When Avishield GI-13 is mixed with:</td></tr>
<tr><td rowspan="3">Avishield IB H120</td><td colspan="2">For the mixed products, the claimed protection against Massachusetts and 793B serotypes of IBV has been demonstrated.</td></tr>
<tr><td>Onset of immunity</td><td>Avishield IB GI-13: 10 days after vaccination
Avishield IB H120: 3 weeks after vaccination</td></tr>
<tr><td>Duration of immunity</td><td>Avishield IB GI-13: 8 weeks after vaccination
Avishield IB H120: 8 weeks after vaccination</td></tr>
<tr><td rowspan="3">Avishield IB H120 and Avishield IB QX</td><td colspan="2">For the mixed products, the claimed protection against Massachusetts and 793B serotypes, and QX-like variants of IBV has been demonstrated.</td></tr>
<tr><td>Onset of immunity</td><td>Avishield IB GI-13: 3 weeks after vaccination
Avishield IB H120: 3 weeks after vaccination
Avishield IB QX: 3 weeks after vaccination</td></tr>
<tr><td>Duration of immunity</td><td>Avishield IB GI-13: 8 weeks after vaccination
Avishield IB H120: 8 weeks after vaccination
Avishield IB QX: 10 weeks after vaccination</td></tr>
</table>

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

Oculonasal use (spray or eye/nasal drop): from one day of age.
In drinking water use: from 7 days of age.

Administer one dose per animal by either coarse spray, eye/nasal drop 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 1 000 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 1 000 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 microns), 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 or with both Avishield IB H120 and Avishield IB QX, use the same total volume of water as for a single application.
For example:

- when mixing two vaccines, 1 000 doses of Avishield IB GI-13 and 1 000 doses of Avishield IB H120 should be reconstituted in a total of 150-300 ml of water;

- when mixing three vaccines, 1 000 doses of Avishield IB GI-13, 1 000 doses of Avishield IB H120 and 1 000 doses of Avishield IB QX 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.
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. By adding approximately 2 grams of skimmed milk powder or 20 ml of liquid skimmed milk per litre of water the virus retains its activity longer.
In order to determine the quantity of water in which 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 the 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 ambient 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. Eye/nasal drop
Reconstitute 1 000 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 one eye and one drop (0.05 ml) into one 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, transient coughing after spray administration and adverse events described in section Adverse events were 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 the 793B serotype of avian infectious bronchitis virus (vaccinal strain V-173/11 belongs to 793B serotype/GI-13 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.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing other substances used in drinking water.

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 ºC - 8 ºC).
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 1 000 doses of vaccine.
Cardboard box with 10 vials of 2 500 doses of vaccine.
Cardboard box with 10 vials of 5 000 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

IZO S.r.l.

7. MARKETING AUTHORISATION NUMBER(S)

VPA25579/004/001

8. DATE OF FIRST AUTHORISATION

29/05/2020

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

09/09/2026

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).