SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IB H120 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 Massachusetts, strain H120, Live $10^{3.5}$ to $10^{4.5}$ 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 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 the detrimental effect resulting from the infection by avian infectious bronchitis virus, serotype Massachusetts on the ciliary activity, which may be manifested in respiratory clinical signs.

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 8 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 the birds in the flock should be vaccinated at the same time.
The vaccine strain can spread to susceptible, unvaccinated chickens for a minimum of 10 days following vaccination. It is possible that the vaccine virus can be spread to non-target susceptible species. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to unvaccinated birds or susceptible species as much as possible.

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 masks with eye protection should be 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 signs[1], Respiratory sound[1]

[1] Tracheal rales for 3-10 days post 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 its local representative 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 GI-13 or with both Avishield IB GI-13 and

Avishield IB QX by coarse spray from one day of age onwards. Read the product information of Avishield IB GI-13 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 IB H120 is mixed with:</td></tr>
<tr><td rowspan="3">Avishield IB GI-13</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 GI-13
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 reconstituted doses corresponds to the number of birds in a 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.
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.
When mixing this product with Avishield IB GI-13 or with both Avishield IB GI-13 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 H120 and 1 000 doses of Avishield IB GI-13 should be reconstituted in a total of 150-300 ml of water;
- when mixing three vaccines, 1 000 doses of Avishield IB H120, 1 000 doses of Avishield IB GI-13 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, breeds, the management practice and weather conditions.
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 into one eye and one drop into one nostril.
For chickens aged from 1 to 14 days of smaller breeds, 4 drops of 25 µl should be used. Administer one drop in each eye (0.05 ml altogether) and then one drop in each nostril (0.05 ml altogether).

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

No adverse reactions other than those listed in section Adverse events have been observed following the 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

To stimulate active immunity in chickens against strains of avian infectious bronchitis virus belonging to Massachusetts serotype.

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 °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:
Carton box with 10 vials of 1 000 doses of vaccine.
Carton box with 10 vials of 2 500 doses of vaccine.
Carton 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 product 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

Vm 43676/4002

8. DATE OF FIRST AUTHORISATION

13 February 2018

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

April 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 20 May 2026