

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{carton box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IB H120, lyophilisate for ocularnasal suspension/use in drinking water, for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:
Attenuated live virus of avian infectious bronchitis,
Massachusetts serotype strain H-120 10^{3.5} to 10^{4.5} EID₅₀

3. PHARMACEUTICAL FORM

Lyophilisate for ocularnasal suspension/use in drinking water

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For ocularnasal, spray or drinking water administration
Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Once reconstituted use within 3 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 °C - 8 °C).

Protect from light.

Do not freeze

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

Administration by a veterinary surgeon or under their direct responsibility

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43676/4002

17. MANUFACTURER’S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IB H120, lyophilisate for ocularnasal suspension/use in drinking water, for chickens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose contains:
Attenuated live virus of avian infectious bronchitis,
Massachusetts serotype strain H-120 10^{3.5} to 10^{4.5} EID₅₀

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1000 doses
2500 doses
5000 doses

4. ROUTE(S) OF ADMINISTRATION

Ocularnasal, spray or drinking water

5. WITHDRAWAL PERIOD (S)

Withdrawal period: Zero days

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
Once reconstituted use within 3 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Avishield IB H120, lyophilisate for oculonasal suspension/use in drinking water, for chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IB H120, lyophilisate for oculonasal suspension/use in drinking water, for chickens

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose contains:

Attenuated live virus of avian infectious bronchitis,
Massachusetts serotype strain H-120

$10^{3.5}$ to $10^{4.5}$ EID₅₀

**EID₅₀ = 50% Embryo infective dose*

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Transient respiratory disturbances, including tracheal rales have been observed very commonly for 3-10 days post vaccination. These did resolve spontaneously and did not need treatment.

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 inform your veterinary surgeon.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

7. TARGET SPECIES

Chickens

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Vaccination:

Coarse spray and oculonasal route: from one day of age

Drinking water route: from 7 days of age

1. By spraying

It is recommended to resuspend 1000 doses of the vaccine in 150 - 300 ml of distilled water. The number of doses diluted 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.

2. Administration in the drinking water

Suspend 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 suspended 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 suspended for the vaccination of chickens in a younger age category (until third week of life), the following are guidelines:

- 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 = $1 \times 7 = 7$ L)

It is important to dissolve 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 immunisation (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. Oculo-nasal administration

Suspend 1000 doses of the vaccine in 100 ml distilled water

A dose of reconstituted vaccine is 0.1 ml, i.e. two drops, irrespective of poultry age, weight and type. Instil one drop into the eye and one drop into the nose opening.

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).

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C - 8 °C).

Protect from light.

Do not freeze

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton.

Shelf life after reconstitution: 3 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only

Special precautions for use in animals:

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 worn by the operator and staff.

Lay:

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

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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 (symptoms, emergency procedures, antidotes):

No adverse reactions other than those listed in section Adverse reaction have been observed following the administration of 10 times the recommended dose of vaccine..

Incompatibilities

Do not mix with any other veterinary medicinal product

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2023

15. OTHER INFORMATION

The vaccine stimulates active immunity in chickens against strains of avian infectious bronchitis virus belonging to Massachusetts serotype.

For animal treatment only– to be supplied only on veterinary prescription
Administration by a veterinary surgeon or under their direct responsibility

Carton box with 10 vials of 1000 doses of vaccine.
Carton box with 10 vials of 2500 doses of vaccine.
Carton box with 10 vials, of 5000 doses of vaccine.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Revised: June 2023
AN: 01938/2022 & 01945/2022

A handwritten signature in black ink, appearing to read 'Dennett', written in a cursive style.

Approved: 12 June 2023