[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IBD INT lyophilisate for oculonasal suspension/use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Infectious bursal disease virus, IM strain VMG 91, Live $10^{4.0}$ to $10^{5.0}$ $TCID_{50}$*

*$TCID_{50}$ = 50% tissue culture infective dose.

Excipients:

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

Cream to reddish coloured lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For active immunisation of chickens (broilers, future layers and breeders), with maternally derived antibodies, to prevent mortality and clinical disease, due to infection caused by infectious bursal disease viruses.

Onset of immunity: 2 weeks after vaccination.
Duration of immunity: 4 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Please refer to section ‘Administration routes and dosage’.
Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The vaccine strain can spread to susceptible, unvaccinated chickens for at least 10 days following vaccination. The vaccine virus has shown the potential to increase in virulence on bird to bird passage

and may cause immunosuppression but does not induce clinical signs of disease. It is very important to take measures to ensure that the vaccine strain does not spread to unvaccinated chickens.

It is possible that the vaccine viruses can be spread to susceptible non-target species.
Care should be taken to ensure that the vaccine virus does not spread to unvaccinated birds. Therefore, all birds in a flock should be vaccinated at the same time to reduce the risk of bird to bird transmission. Vaccinated birds should not be mixed with unvaccinated birds. Hygiene measures should be taken to prevent spread to other flocks. Vaccination of all chickens on the premises is recommended.
Housing needs to be disinfected prior to restocking.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash and disinfect hands and equipment after vaccination.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens.

Very common (>1 animal / 10 animals treated):	Bursa of Fabricius lymphocyte depletion[a]

[a] Mild to moderate; 7 days after vaccine take (bursal lesion score 2.4). This depletion decreases and is followed by lymphocyte repopulation and complete regeneration of the bursa by day 28 post vaccination (bursal lesion score 0.2).

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

3.8 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.

3.9 Administration routes and dosage

One dose of vaccine should be administered to each chicken in drinking water, or by the oculonasal route from 8 days of age depending on the level of maternally derived antibodies (MDA) in the flock. Lyophilisate reconstituted in 100 mL of water appears as non-transparent suspension with low precipitation.

The optimal vaccination date is influenced by a number of factors, such as status of MDA, type of bird, infection pressure, housing and management conditions.
MDA can interfere with the immunity induced by live infectious bursal disease (IBD) vaccines, so the optimum age for vaccination depends on both the level of residual MDA against IBD virus in the flock

and the ability of the vaccine strain to induce the required level of immunity in the presence of MDA. To predict the age when the MDA titre has sufficiently decreased to allow effective vaccination ("break-through titre"), testing of serum samples of at least 18 chicks by serology and application of the "Deventer formula" is advised. A break-through titre of 125 should be used.

The Deventer formula is as follows:

Vaccination age = { (log2 titre bird% - log2 breakthrough) x t _ } + age at sampling + correction 0-4

In which:

- bird% = ELISA titre of the bird representing a certain percentage of the flock
- breakthrough = breakthrough (ELISA) titre of the vaccine to be used
- t _ = half-life time (ELISA) of the antibodies in the type of chickens being sampled
- age at sampling = age of the birds at sampling
- correction 0-4 = extra days when the sampling was done at 0 to 4 days of age.

A high homogeneity of MDA levels in the flock is important to define the correct timing of vaccination and guarantees a better active immune response to the vaccine. In case of a non-homogenous flock where antibody levels vary widely between birds (i.e. CV greater than 30%), or the stock originates from different sources, it is recommended to repeat the vaccination.
In such cases, timing of the first and second vaccination should be determined simultaneously, with two different percentages (corresponding to the percentages of the flock that can be efficaciously vaccinated) of all serum samples collected on the sampling day, using the Deventer formula.

1. In drinking water use

- Reconstitute the vaccine in a small amount of 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. Where the number of birds is between the standard dosages, the next higher dosage should be used.
- The vaccine should be reconstituted immediately before use.
- Measure the correct volume of water for the number of birds to be vaccinated. The volume of water for dilution depends on the age of the birds, breed, housing conditions and weather conditions.
- The reconstituted vaccine should be diluted in the amount of water which will be consumed within 1.5 to 2.0 hours (taking into account the different types of drinking systems for poultry).
- In order to determine the quantity of water in which the vaccine will be diluted, measure the volume of water consumed within a two hours period one day before vaccination.
- As a guideline for younger chickens (until 3rd week of life), apply the reconstituted vaccine to cold and fresh water at the rate of 1 000 doses of vaccine to 1 litre of water per day of age for 1 000 chickens, e.g. 8 litres would be needed for 1 000, 8 day old chickens.
- In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to immunisation (birds drinking behaviour varies, depending on the air temperature, type of birds, breed, management, weather conditions).
- The drinking system should be clean, without traces of chlorine, other disinfectants or impurities.
- If needed, turn the lights down low when the water is turned off. After the vaccine is in the drinking system, increase light intensity again. Increased light intensity will stimulate the birds to look for food and water.
- Always make sure that there is food available when vaccinating. Birds will not drink if they have no food to eat.

2. Oculonasal use

- 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, irrespective of poultry age, weight and type. Instill one drop into an eye and one drop into a nostril.

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 those 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: QI01AD09

To stimulate active immunity against infectious bursal disease virus in chickens.

The vaccine strain is an intermediate strain with an average bursal lesion score of 0.2 at 28 days after administration of 10-times the maximum dose.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after reconstitution according to directions: 3 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

The vaccine is filled into 4 ml or 10 ml colourless glass vials (type I), which are closed with brombutyl 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 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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}>

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

<{DD/MM/YYYY}>

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{carton box with 10 glass vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IBD INT lyophilisate for oculonasal suspension/use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:
Infectious bursal disease virus, IM strain VMG 91, Live $10^{4.0}$ to $10^{5.0}$ $TCID_{50}$

3. PACKAGE SIZE

10 x 1 000 doses
10 x 2 500 doses
10 x 5 000 doses

4. TARGET SPECIES

Chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use or oculonasal 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 in a refrigerator.
Protect from light.
Do not freeze.

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

Genera d.d.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Glass vials with 1000, 2500 or 5000 doses}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Avishield IBD INT

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose contains:
Infectious bursal disease virus, IM strain VMG 91, Live $10^{4.0}$ to $10^{5.0}$ $TCID_{50}$

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 IBD INT lyophilisate for oculonasal suspension/use in drinking water for chickens

2. Composition

Each dose contains:

Active substance:
Infectious bursal disease virus, IM strain VMG 91, Live $10^{4.0}$ to $10^{5.0}$ $TCID_{50}$*

*$TCID_{50}$ = 50% tissue culture infective dose.

Cream to reddish coloured lyophilisate.

3. Target species

Chickens.

4. Indications for use

For active immunisation of chickens (broilers, future layers and breeders), with maternally derived antibodies, to prevent mortality and clinical disease, due to infection caused by infectious bursal disease viruses.

Onset of immunity: 2 weeks after vaccination.
Duration of immunity: 4 weeks after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Please refer to section 'Dosage for each species, routes and method of administration'.
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
The vaccine strain can spread to susceptible, unvaccinated birds for at least 10 days following vaccination. The vaccine virus has shown the potential to increase in virulence on bird to bird passage and may cause immunosuppression but does not induce clinical signs. It is very important to take measures to ensure that the vaccine strain does not spread to unvaccinated birds.

It is possible that the vaccine viruses can be spread to susceptible non-target species.
Care should be taken to ensure that the vaccine virus does not spread to unvaccinated birds. Therefore, all birds in a flock should be vaccinated at the same time to reduce the risk of bird to bird transmission. Vaccinated birds should not be mixed with unvaccinated birds. Hygiene measures

should be taken to prevent spread to other flocks. Vaccination of all chickens on the premises is recommended.
Housing needs to be disinfected prior to restocking.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands and equipment after vaccination.

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

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:
After the administration of a 10-fold overdose, no adverse reactions other than those described in section 'Adverse events' were observed.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens

Very common (>1 animal / 10 animals treated):	Bursa of Fabricius lymphocyte depletion[a]

[a] Mild to moderate; 7 days after vaccine take (bursal lesion score 2.4). This depletion decreases and is followed by lymphocyte repopulation and complete regeneration of the bursa by day 28 post vaccination (bursal lesion score 0.2).

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 the 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

One dose of vaccine should be administered to each chicken in drinking water, or by the oculonasal route from 8 days of age depending on the level of maternally derived antibodies (MDA) in the flock.

The optimal vaccination date is influenced by a number of factors, such as status of MDA, type of bird, infection pressure, housing and management conditions.
MDA can interfere with the immunity induced by live infectious bursal disease (IBD) vaccines, so the optimum age for vaccination depends on both the level of residual MDA against IBD virus in the flock and the ability of the vaccine strain to induce the required level of immunity in the presence of MDA. To predict the age when the MDA titre has sufficiently decreased to allow effective vaccination (break-through titre) testing of serum samples of at least 18 chicks by serology and application of the "Deventer formula" is advised. A break-through titre of 125 should be used.

The Deventer formula is as follows:

Vaccination age = { (log2 titre bird% - log2 breakthrough) x t _ } + age at sampling + correction 0-4

In which:
- bird% = ELISA titre of the bird representing a certain percentage of the flock
- breakthrough = breakthrough (ELISA) titre of the vaccine to be used
- t _ = half-life time (ELISA) of the antibodies in the type of chickens being sampled
- age sampling = age of the birds at sampling
- correction 0-4 = extra days when the sampling was done at 0 to 4 days of age.

A high homogeneity of MDA levels in the flock is important to define the correct timing of vaccination and guarantees a better active immune response to the vaccine. In case of a non-homogenous flock where antibody levels vary widely between birds (i.e. CV greater than 30%), or the stock originates from different sources, it is recommended to repeat the vaccination.
In such cases, timing of the first and second vaccination should be determined simultaneously, with two different percentages (corresponding to the percentages of the flock that can be efficaciously vaccinated) of all serum samples collected on the sampling day, using the Deventer formula.

9. Advice on correct administration

Lyophilisate reconstituted in 100 mL of water appears as non-transparent suspension with low precipitation.

1. In drinking water use
- Reconstitute the vaccine in a small amount of 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. Where the number of birds is between the standard dosages, the next higher dosage should be used.
- The vaccine should be reconstituted immediately before use.
- Measure the correct volume of water for the number of birds to be vaccinated. The volume of water for dilution depends on the age of the birds, breed, housing conditions and weather conditions.
- The reconstituted vaccine should be diluted in the amount of water which will be consumed within 1.5 to 2.0 hours (taking into account the different types of drinking systems for poultry).
- In order to determine the quantity of water in which the vaccine will be diluted, measure the volume of water consumed within a two hours period one day before vaccination.
- As a guideline for younger chickens (until 3rd week of life), apply the reconstituted vaccine to cold and fresh water at the rate of 1 000 doses of vaccine to 1 litre of water per day of age for 1 000 chickens, e.g. 8 litres would be needed for 1 000, 8 day old chickens.
- In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to immunisation (birds drinking behaviour varies, depending on the air temperature, type of birds, breed, management, weather conditions).
- The drinking system should be clean, without traces of chlorine, other disinfectants or impurities.
- If needed, turn the lights down low when the water is turned off. After the vaccine is in the drinking system, increase light intensity again. Increased light intensity will stimulate the birds to look for food and water.
- Always make sure that there is food available when vaccinating. Birds will not drink if they have no food to eat.

2. 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, irrespective of poultry age, weight and type. Instill one drop into an eye and one drop into a nostril.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.

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

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.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:

Genera d.d.
Svetonedeljska cesta 2, Kalinovica
10436 Rakov Potok
Croatia
<Tel: >

<Local representatives <and contact details to report suspected adverse reactions>:>

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

17. Other information

The vaccine stimulates active immunity against infectious bursal disease virus in chickens.