. 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:
Live avian infectious bronchitis virus, variant strain V-173/11: $10^{2.7}$ - $10^{4.6}$ EID_{50}*

* EID_{50} = 50% Embryo infective dose

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension/use in drinking water.
Cream to yellow coloured lyophilisate

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the 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: 56 days after vaccination

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
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.

The vaccine strain can spread to susceptible, unvaccinated chickens for a minimum of 28 days following vaccination. It is possible that the vaccine virus can be 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 by the operator and staff.

4.6 Adverse reactions (frequency and seriousness)

Tracheal rales have been observed very commonly between 1 and 13 days after oculonasal vaccination. If they occur, they resolve spontaneously and do not need treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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).

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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.

1. Coarse spray
It is recommended to resuspend 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 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.

2. In drinking water use
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, 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 suspended 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 resuspend 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 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
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 (0.05 ml) into the eye and one drop (0.05 ml) into the nose opening. Ensure that the nasal drop is inhaled before releasing the bird.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

After the administration of a 10 fold overdose, transient coughing after spray administration and adverse reactions described in section 4.6 were observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccines for domestic fowl, avian infectious bronchitis virus
ATC vet code: QI01AD07

To stimulate active immunity in chickens against 793B serotype of avian infectious bronchitis virus (vaccinal strain V-173/11 belongs to 793B serotype/GI-13 lineage).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone K 25
Bacto-peptone
Monosodium glutamate
Potassium dihydrogen phosphate
Potassium hydroxide
Dextran 40 000
Sucrose

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after reconstitution according to directions: 3 hours.

6.4. Special precautions for storage

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

6.5 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 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

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

Vm No: 43676/4005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.