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:
Attenuated live virus of avian infectious bronchitis,
Massachusetts serotype, strain H-120 $10^{3.5}$ to $10^{4.5}$ 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 coloured lyophilisate

4 CLINICAL INFORMATION

4.1 Target species

Chickens

4.2 Indications for use, specifying the 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

4.3 Contraindications

None.

4.4 Special precautions for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

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 worn by the operator and staff.

4.6 Adverse reactions (frequency and seriousness)

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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 Interactions with other medicinal products and other forms of interactions

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 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 x 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).

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

No adverse reactions other than those listed in section 4.6 have been observed following the administration of 10 times the recommended dose of vaccine**.**

4.11 Withdrawal period

Zero days.

5 IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals, immunologicals for aves, domestic fowl, live viral vaccines, avian infectious bronchitis virus
ATC vet code: QI01AD07
To stimulate active immunity in chickens against strains of avian infectious bronchitis virus belonging to Massachusetts serotype.

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: 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 brombutyl rubber stoppers and sealed with aluminium caps.

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.

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 national requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT