

ORNIBRON

lyophilizate for suspension for domestic fowl

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

Bioveta, a. s., Komenského 212/12,
683 23 Ivanovice na Hané, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORNIBRON, lyophilizate for suspension for domestic fowl

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

One vaccination dose contains:

Active substances:

Virus bronchitis infectiosae avium H120 min.
10^{3.0} EID₅₀, max. 10^{3.5} EID₅₀
* EID₅₀ – 50% infection dose for chicken embryos

Excipients:

Lyophilization medium: gelatine, saccharose, water for injections

4. INDICATION(S)

Active immunization of chickens from the one day of age against infectious bronchitis. After spray vaccination of one-day-old susceptible chickens the onset of immunity was established 10-14 days later. Chickens are revaccinated by spray or administration in drinking water, most frequently at the age of 4 weeks and between 12 and 14 weeks of age. If the prescribed vaccination schedule is observed, the immunity lasts until the end of laying season.

5. CONTRAINDICATIONS

It is not recommended to vaccinate sick poultry and layers during the laying season.

6. ADVERSE REACTIONS

None known.

If you observe any serious adverse reactions or other reactions, that are not listed in this package insert, report them please to your veterinary surgeon.

7. TARGET SPECIES

Domestic fowl.

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

Individual ocular administration:

Reconstituted vaccine is administered in a single drop on the conjunctival mucosa of individual birds.

In one-day-old chickens the vaccine is administered to the nasal mucosa by dipping their beaks into the vaccine solution.

Mass spray application:

The vaccine is administered diluted with water for injection, using a spray gun generating microdroplets.

Mass application to drinking water:

The vaccine is administered dissolved in a quantity of drinking water that can be drunk by the poultry within 1 to 2 hours after dilution of the vaccine.

To induce solid immunity, one-day-old chickens should be vaccinated by spraying. Chickens are revaccinated by spraying or administration in drinking water, most frequently at the age of 4 weeks and between 12 and 14 weeks of age.

9. ADVICE ON CORRECT ADMINISTRATION

Spray vaccination ensures better immunity than the vaccine in drinking water. One-day-old chickens should be vaccinated by application of a coarse spray, sprayed evenly over an appropriate number of poultry from a distance of 30-50 cm. Too fine microdroplets (aerosol fog) cause inhalation of the vaccine virus into the lower airways and, consequently, development of the respiratory disease.

The aerosol application is suitable only for revaccination of older poultry and spray mist is generated through a spray gun in the area of poultry.

For oral administration the vaccine can be diluted only in sound cold drinking water free of antiseptics and disinfectants. Increased temperature and the volume of antiseptics and disinfectants in water reduce significantly the content of the vaccine virus in a dose.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Keep in a dry and dark place at a temperature of 2 to 8 °C.

The vaccine should not be exposed to long-term temperatures above 8 °C.

Do not use after expiring of the expiration period stated on the etiquette.

Shelf life after reconstitution: Consume immediately.

12. SPECIAL WARNING(S)

No information is available on the safety and efficacy of this vaccine when administered concurrently with other veterinary medicinal products. Decision about using this vaccine before or after any other veterinary medicinal product must be based on consideration of individual cases.

It is not recommended to vaccinate sick poultry and layers during the laying season.

Special procurement determined to the persons, that dose the veterinary drug product to the animals

During the vaccination it is necessary to avoid the exposition to the virus and during spraying to use the protective goggles and mask. After finish of vaccination it is necessary to wash and disinfect the hands. The used equipment must be washed and the residui of vaccine to inactivate by the active disinfection product. Or by impact of heat (boiling and incineration).

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

September 2020

15. OTHER INFORMATION

After vaccination of the live virus against the infectious bronchitis the nesterile immunity forms, with which the persistence of the vaccination virus in organism is not excluded for a period of several days or weeks. The virus against infectious bronchitis of poultry is not transmissible to humans.

Package:

200 doses, 500 doses, 1000 doses, 2500 doses

10 × 200 doses, 10 × 500 doses, 10 × 1000 doses, 10 × 2500 doses

Not all sizes of package may be on the market

For animals only - to be supplied only on veterinary prescription.



Dimensions (mm): A6 (105 × 148 mm) duplex printing
Colours: black
Prepared by: Hanáková
Date: 30. 10. 2020

Approved by:

Date: