

ORNIBUR Intermediate, 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

ORNIBUR Intermediate, lyophilizate for
suspension for domestic fowl

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

Active substances:

Virus bursitidis infectious avium
strain IBDV OP 23 ,
min. $10^{4.0}$ TCID₅₀ , max. $10^{5.3}$ TCID₅₀ in one dose
* TCID₅₀ – 50% infectious dose for tissue
culture

Excipients: Lyophilization medium

4. INDICATION(S)

Active immunization of chickens from the
seven days of age against aviary infectious
bursitidis.

Immunity starts in the chickens within 14 days
after vaccination and persists in the fattening
chickens till the end of the fattening period.

5. CONTRAINDICATIONS

It is not recommended to vaccinate sick poultry.

6. ADVERSE REACTIONS

Not known.

7. TARGET SPECIES

Domestic fowl.

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

Individual application:

The vaccine is diluted in sterile saline or in
water for injection. One drop of the diluted
vaccine is administered to the conjunctival
pouch – intraconjunctivally – to the individual
birds.

Mass application:

The vaccine is administered in diluted form in
such an amount of drinking water that the fowls
consume within two hours from vaccine
dilution.

It is convenient to vaccinate the chickens from
hens with fair passive immunity, vaccinated

with inactivated vaccines, at the age of 21 to
28 days. Chickens of endangered breeds are
recommended to be vaccinated as early as in
the second week of age, and re-vaccinated one
to two weeks later, preferably on the basis of
serological examination of one-day-old
chickens.

9. ADVICE ON CORRECT ADMINISTRATION

In case of oral vaccination, the vaccine may
only be diluted in cold and uncontaminated
drinking water, free of antiseptics and
disinfection substances. Elevated temperature
and content of antiseptic and disinfection
substances in water significantly reduce the
content of the vaccination virus in a dose.

10. WITHDRAWAL PERIOD(S)

Without withdrawal period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C - 8 °C).

The vaccine should not be exposed to
long-term temperatures above 8 °C.
Do not use this veterinary medicinal product
after the expiry date which is stated on the
label.

Shelf life after reconstitution: within 2 hours.

12. SPECIAL WARNING(S)

Use usual aseptic measures during all
procedures related to the product
administration.

The safety studies proved that the vaccination
viruses of the strain IBDV OP-23 are safe to
target animals and passaging on the target
animal does not increase their virulence or
produce clinical symptoms of disease.

Therefore, it is not necessary to take any
special veterinary and animal husbandry
actions in respect of the vaccination.

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.

Veterinary medicinal product must not be
mixed with other veterinary medicinal products.
Is not indicated vaccination of laying hens in
lay.

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

Avoid exposure to the virus during vaccination
and wear protective goggles and a mask during
the spray application. Wash and disinfect your
hands after the vaccination is finished. Wash
used equipment and inactivate vaccine
residues with an effective disinfectant, or by
heat treatment (boiling and burning).

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

Dispose of waste material by boiling,
incineration or immersion in an appropriate
disinfectant approved for use by the competent
authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

For animal treatment only.

To be supplied only on veterinary prescription.

The vaccine is supplied in glass vials,
hydrolytic class I, comply with Ph.Eur.;
closed with rubber lyophilisation stopper and
aluminium cap.

Package:

500 doses, 1000 doses, 2000 doses, 5000
doses
10 × 500 doses, 10 × 1000 doses,
10 × 2000 doses, 10 × 5000 doses

Not all pack sizes may be marketed.



Dimensions (mm):

Colours:

Prepared by:

Date:

A6 (105 × 148 mm) duplex printing

black

Hanáková

02. 11. 2020

Approved by:

Date: