

ORNIPRIM, 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

ORNIPRIM, lyophilizate for suspension for
domestic fowl

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

One vaccination dose contains:

Active substance:

Paramyxovirus pseudopestis avium, strain
Bio 52: NDV B1

min. $10^{6.0}$ EID₅₀ - max. $10^{7.5}$ EID₅₀
* EID₅₀ – 50% infection dose for chicken
embryos

Excipients:

Lyophilization medium

4. INDICATION(S)

Active immunization of chickens one to
fourteen days old against Newcastle poultry
disease.

Immunity is developed in one week after
vaccination and lasts at least five weeks.

5. CONTRAINDICATIONS

It is not recommended to vaccinate poultry
that is already ill.

6. ADVERSE REACTIONS

Not known.

7. TARGET SPECIES

Domestic fowl.

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

Individual application:

200 vaccine doses are diluted in 10 ml
water for injection. Administer one drop of
the diluted vaccine into the conjunctiva sac

of individual birds. In the case of one-day-
old chickens, apply the vaccine on to the
nasal mucosa by dipping the beak into the
vaccination solution.

Mass application by spray:

Administer the vaccine diluted in drinking
water by means of a micro-droplet-making
sprayer.

1000 vaccine doses are diluted in 200 to
250 ml water for injection.

9. ADVICE ON CORRECT ADMINISTRATION

Vaccinate chickens by application of a
"coarse spray" evenly sprayed over
equivalent number of poultry from the
distance of 30 to 50 cm. Too fine droplets
(aerosol fog) cause inhalation of the
vaccination virus into the lower airways
and, as a consequence, development of a
respiratory disease.

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).

Do not expose the vaccine to the
temperatures above 8 °C for a long time.
Do not use this veterinary medicinal
product after the expiry date which is stated
on the label.

Shelf life after reconstitution: use
immediately.

12. SPECIAL WARNING(S)

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

The vaccination virus of avian Newcastle
disease, strain Bio 52: NDV B reproduce
and proliferate in the organism of
vaccinated chickens after application.

Several days after vaccination, the
vaccination viruses are excreted into the
environment to a limited extent, where they
can attack other sensitive animals.

The safety studies proved that the
vaccination viruses 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
compatibility of this vaccine with any other.
Therefore the safety and efficacy of this
product when used with any other (either
when used on the same day or at different
times) has not been demonstrate.
Do not mix with any other vaccine/
immunological product.

The safety of the veterinary medicinal
product has not been established during
lay.

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

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

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

For animal treatment only.

To be supplied only on veterinary
prescription.

3 ml and 9 ml vials of type I hydrolytic glass
containing 200, 500, 1000, 2500 doses of
freezedried vaccine. The vial is closed with
a rubber bung for lyophilization and sealed
with a aluminium cap.

Vaccine is packaged in plastic or cardboard
box:

Individual packaging:
1 × 200 doses, 1 × 500 doses,
1 × 1000 doses, 1 × 2500 doses

Group packaging:
10 × 200 doses, 10 × 500 doses,
10 × 1000 doses, 10 × 2500 doses

Not all pack sizes may be marketed.

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



Dimensions (mm): A6 (105 × 148 mm) duplex printing
Colours: black
Prepared by: Hanáková
Date: 10. 11. 2020

Approved by:

Date: