

ORNIMIX CLONE B1+H120,

lyophilizate for the preparation of 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,
683 23 Ivanovice na Hané, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORNIMIX CLONE B1+H120, lyophilizate
for the preparation of suspension
for domestic fowl

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One vaccination dose contains:

Active substances:

Paramyxovirus pseudopestis avium,
strain Bio 52:

NDV B1 min. $10^{6.0}$ EID₅₀ – max. $10^{7.5}$ EID₅₀

Virus bronchitidis infectious avium,
strain Bio 53:

IBV H 120 min. $10^{3.0}$ EID₅₀ – max. $10^{4.8}$ EID₅₀

Excipients: Nutrimentum pro lyophilisatione.

4. INDICATION

For active immunization of fowl against
Newcastle avian disease and infectious
bronchitis of Massachusetts type.

For prevention of infection and mortality
caused by Newcastle disease virus and by
infectious bronchitis virus.

Onset of immunity:

The immunity against Newcastle disease
and infectious bronchitis starts not later
than 14 and 7 days after primovaccination,
respectively, and maternal antibodies have
no negative influence on the efficacy of
vaccination.

The immunity lasts for 6 weeks after spray
and ocular nasal primovaccination and
4 weeks after peroral primovaccination.

Time of immunity duration:

After revaccination, the immunity persists
for 6 weeks as a minimum. The level
of immunity against

Newcastle disease can be evaluated after
revaccination on the basis of serological
examination.

5. CONTRAINDICATIONS

Only healthy animals should be vaccinated.
Do not use in animals that are showing signs
of disease.

6. ADVERSE REACTIONS

Post-vaccination reactions may occur in
particular after unsuitable vaccine application
by spraying, because fine micro-droplets
(aerosol mist) cause inhalation of the
vaccination virus into the lower air passages
and respiratory disease as its consequence.

7. TARGET SPECIES

Domestic fowl – from the age of one day.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Individual ocular nasal application:

The lyophilized vaccine is dissolved in
a sterile solvent (e.g. water for injections).
The vaccine is applied by a common
eye-dropper onto the conjunctiva mucosa
or nostril of individual birds; it is necessary
to provide breath suction of the droplet by
the animal.

Mass spray application:

Distilled water or cool purified water free
from chlorine and iron residues is used for
vaccine dissolving. The device, specified
exclusively for this purpose and generating
droplets (diameter of 30 to 100 µm) is used
for vaccination. For one day chickens
1000 doses will be dissolved in the
200–250 volume; the sprayer nozzle has to
be set to generation of a "coarse spray" =
small droplets falling as a fine rain. For older
poultry 1000 doses are dissolved in one litre
of water and the sprayer nozzle is set to
generation of fine droplets. The vaccination
solution is sprayed uniformly at the distance
of 30 to 50 cm above the adequate number
of animals under soft lighting.

Mass application into potable water:

It is recommended to vaccinate the chickens
from the 4th day after hatching, when reliable
intake of the vaccination dose in potable
water can be assumed. The vaccine is
administered in the morning, when the
poultry is thirsty enough. The vaccine is

administered (depending on age) dissolved
in such potable water quantity which will be
consumed within 2 hours.

Re-vaccination is carried out every six weeks
after the first ocular nasal or spray
administration and in 4 weeks after the first
peroral vaccination. Further vaccinations
are carried out every six weeks.

In the regions with endemic occurrence of
the Newcastle disease re-vaccination should
be realized in four-week intervals and the
first vaccination shall be carried out
ocular nasally or by spraying; before
egg-laying the inactivated vaccine against
Newcastle disease and avian infectious
bronchitis should be applied.

9. ADVICE ON CORRECT ADMINISTRATION

Content of antiseptics and disinfectants,
presence of chlorine and iron in the water
used for vaccine dissolving affects the
vaccination virus negatively and has adverse
impact on vaccine efficiency. Virus activity
can be potentiated by adding the skimmed
cow's milk – 50 ml and/or powdered milk –
2 g/l of the vaccination solution. The
technical device specified for vaccine
application, incl. the watering place must be
kept clean, free from any detergent and
disinfectant residues.

Special precautions for use in animals

Only healthy animals should be vaccinated.

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).

10. WITHDRAWAL PERIOD

Without withdrawal period.

11. SPECIAL STORAGE PRECAUTIONS

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

Shelf-life of the veterinary medicinal product
in the intact container: 2 years

Shelf-life after first opening: consume
immediately.

Shelf-life after dilution: within 3 hours.

12. SPECIAL WARNING

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

The vaccination virus of avian Newcastle
disease, strain Bio 52: NDV B, and the
vaccination virus of avian infectious
bronchitis, strain Bio 53: IBV H120,
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 demonstrated.
Do not mix with any other vaccine/
immunological product.

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

December 2008.

15. OTHER INFORMATION

The vaccine is supplied in glass vials type I
complying with Ph.Eur., closed with a rubber
bung for lyophilization and sealed with a
aluminium cap.

Package:

200 doses, 500 doses, 1000 doses,
2 500 doses, 5000 doses, 10×200 doses,
10×500 doses, 10×1000 doses,
10×2500 doses, 10×5000 doses.

Not all pack sizes may be marketed.

bioveta



Rozměr š × v (mm):

Barevnost:

Připravil:

Datum:

2 x A6

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Michlíček

17. 2. 2012

Schválil(a):

Dne: