

VAXXON H120-CLONE

Lyophilisate for drinking water/oculonasal suspension for chickens



NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

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NAME OF THE VETERINARY MEDICINAL PRODUCT

VAXXON H120-CLONE, lyophilisate for drinking water/oculonasal suspension for chickens.

STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each dose of reconstituted vaccine contains:

Active substance:

- Live attenuated Infectious Bronchitis virus strain H120: $\geq 3.0 \log_{10} \text{EID}_{50}^*$
- Live attenuated Newcastle Disease virus strain CLONE: $\geq 6.0 \log_{10} \text{EID}_{50}^*$

*EID₅₀=embryo infectious dose 50%

INDICATION

For the active immunisation of chickens against Infectious Bronchitis and Newcastle disease.

Onset of immunity: 2 weeks.

Duration of immunity: 8 weeks

CONTRAINDICATIONS

Do not use in unhealthy birds.

Do not use in the case of hypersensitivity on the active substances or any of excipients.

ADVERSE REACTIONS

Not noted.

If serious adverse reactions or reactions not mentioned in the leaflet occur, please inform the physician.

TARGET SPECIES

Chickens.

DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

The vaccine can be administered to chickens from 1 day of age in drinking water or oculonasal route (by eye drop instillation or spraying).

Administer a second dose of vaccine after about three weeks.

For laying hens and breeders a third dose of vaccine at around 10 weeks of age is recommended.

Reconstitution of the vaccine

Remove the aluminum cap from vaccine vial and reconstitute the lyophilized tablet.

Drinking water:

- remove stopper from vial and fill with 2-3 ml of deionized or drinking water
- replace stopper and shake until dissolved
- add the reconstituted vaccine to the adequate volumes of water for the vaccination depends on the number of doses and the equipment used.
- administer immediately after reconstitution within 2 hours.

Oculonasal:

Eye drop instillation:

- dissolve the vaccine in physiological saline solution or sterile distilled water.
- administer by means of a standardized dropper.

Spray:

- utilize a sprayer producing droplets of adequate dimension (in a day-old chicks as a coarse spray; in three weeks old and above as fine spray)
- spray about 1 meter of distance from the birds.

ADVICE ON CORRECT ADMINISTRATION

Special precautions for use in animals

- all equipment used for vaccination is carefully cleaned
- the water containers should be clean and free from organic waste (food and/or faeces), traces of disinfectants/metal ions and medicinal products that can inactivate the virus
- be sure the water is free of disinfectants and chlorine
- the reconstituted vaccine should be used immediately and consumed within 2 hours
- all animals must have access to drink at the same time
- do not expose the water containing vaccine to heat sources (brooding lamps, sun) or intense light sources.

WITHDRAWAL PERIOD

Zero days.

SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton after EXP. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: use within 2 hours.

SPECIAL WARNINGS

Special warnings for each target species:

The vaccine virus will spread to in-contact birds. Care should be taken to prevent the vaccine virus to spread to unvaccinated birds. Under extreme disease pressure and challenge by variant viruses, fully immune birds may still succumb to disease. Therefore,

successful vaccination is not synonymous with full protection under all conditions of disease challenge.

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

- Administer the veterinary medicinal product with caution
- Live attenuated Newcastle Disease virus can cause conjunctivitis in humans
- Personal protective equipment consisting of protective gloves and glasses should be worn when handling the vaccine
- Wash and disinfect hands after use
- People with known hypersensitivity should avoid contact with the veterinary medicinal product
- The vaccination equipment should be disinfected before re-using or discarded

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

Overdose (symptoms, emergency procedures, antidotes):

No symptoms were observed after the administration of a 10-fold dose of vaccine.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Dispose of waste material in accordance with local requirements.

OTHER INFORMATION

Pack sizes:

10 glass vials of 1000 or 2500 doses in a cardboard box.

Not all pack sizes may be marketed.

Immunological properties:

Live attenuated viral vaccine for active immunization against avian Infectious Bronchitis and Newcastle Disease.