368278 R1

AVIAN INFECTIOUS BRONCHITIS VACCINE, LIVE, I.P

NOT FOR HUMAN USE FOR ANIMAL TREATMENT ONLY

WARNING: To be sold by retail on the prescription of a "Veterinary Doctor" only

Nobilis® IB Ma5 is a live, freeze dried vaccine against Infectious Bronchitis of Poultry.

Composition:

Each dose contains $% 10^{-1}$ at least 3.0 \log_{10} EID_{50} per bird dose of Live Avian Infectious Bronchitis virus strain Ma5, in a stabilizer

Administration:

The vaccine may be delivered as a lyophilized pellet in a glass vial or as lyophilized spheres in cups. In case of the latter presentation the cups must contain at least 3 spheres. In case of the product presented in cups, do not use the product if the contents are brownish and stick to the container as this indicates that the integrity of the container has been breached. Each container should be used immediately and completely after opening.

A.Spray method:

The vaccine should be dissolved in cool, clean water which is free of iron and chlorine. The vials should be opened under the water or the content of the cup(s) should be poured into the water. In both cases mix the water containing the vaccine well before use. After reconstitution the suspension looks clear. The spray apparatus should be free from sediments, corrosion and traces of disinfectants (preferably use it for vaccination purposes only). The vaccine medicated water should be spread evenly over the correct number of birds, at a distance of 30 to 40 cm, preferably when the birds are sitting together in dim light.

For day old chicks, use 0.25 litre of water per 1000 birds and set the nozzle to produce fine droplets falling like rain.

For <u>older birds</u>, dissolve 1000 doses per litre of water and set the nozzle to produce fine droplets. (Aerosol generators should be used only when this is known to be safe to the birds)

B. Intranasal / intraocular instillation:

Dissolve the vaccine in a physiological saline solution (Usually 30ml per 1000 doses) & administer by mean of a standardized dropper. One drop should be applied from a height of a few centimeters on to one nostril or one eye. The handler should ensure that the nasal drop is inhaled by the bird.

 ${\bf Note:}$ For intranasal/intraocular administration a special diluent, Diluent Oculo Nasal is available.

C. Drinking water:

The vials should be opened under water or the content of the cup(s) should be poured into the water. In both cases mix the water containing the vaccine well before use. After reconstitution the suspension looks clear. The vaccine should be dissolved in cool, clean water which is free of iron and chlorine. By adding 2 gram skimmed milk powder per liter water the virus retains its activity much longer.

Ensure uptake of all the vaccine-medicated water in 2 hours. Depending on the weather conditions, it may be advisable to deprive the birds of water prior to vaccination.

A sufficient number of water containers to provide adequate drinking space is essential. These should be clean and free from traces of detergent and disinfectants. Dissolve 1000 doses in as many litres of waters as the age of birds, in days, to a maximum of 40 litres.

The vaccine should be given in early mornings this is the main period of drinking or the cool period on a hot day. When vaccinating larger flocks, it is advisable to start by dissolving only part of the vaccine. If vaccine is administered through a central water supply or a proportioner, great care should be taken. For number of birds between standard dosages, the next higher dose should be chosen.

 $\underline{Note:}$ Administration by coarse spray or the oculo / nasal route gives the best response. These should be method of choice, especially when vaccinating young birds.

The vaccine can be administered through the drinking water. The vaccine should be dissolved in an amount of water which will be consumed by the animals within approximately 2 hours.

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Vaccination programme:

The optimum time and method of administration depend largely upon the local situation. Therefore, the advice of the veterinarian should sought. The vaccine is safe to use from 1 day of age onwards.

<u>Guidelines:</u>

Broilers : Vaccination at day old, coarse spray or intranasal /intraoccular. Layers & breeders : Vaccination at day old, coarse spray or intranasal /intraocular. Re-vaccination at approximately 6 weeks of age by spay, Intraocular/intranasal or drinking water administration.

Immunity

After a first vaccination, an adequate immunity against the Massachusetts type of IB will last for approximately 6 weeks provided that the vaccine is properly administered in healthy chicks/birds.

Vaccination reactions

Reactions upon vaccination with IB vaccine $\mathsf{Nobilis}^{\textcircled{0}}$ Ma5 are generally mild or absent.

Intensity and duration of the vaccination reaction are dependent on the health condition of the birds. Hygiene and management are also important in the post vaccination period in order to minimize adverse reactions. It has been demonstrated, that vaccination during the laying period does not cause any adverse reaction in the birds. A transient drop in egg production may be caused by any disturbance of the birds.

Withdrawal period: None

- List of Excipients:
- Sorbitol
- Hydrolysed gelatine
- Pancreatic digest of casein
- Disodium phosphate dihydrate
- Water for injection

Precautions:

- Wash and disinfect hands and equipment after vaccinating. Any surplus vaccine should be destroyed by burning or by boiling.
- Vaccinate healthy birds only.
- Each container should be used immediately and completely after opening.

Storage conditions:

Store at +2°C +8°C

Incompatibilities

None

Shelf life in the medical products as packaged for sale

In freeze dried form: at least 24 months

Shelf life after dilution or reconstitution according to the direction After reconstitution: 2 hours

Nature and contents of the container:

-Vial of hydrolytical type I glass containing the freeze-dried pellet. The vial is closed with a halogenobutyl rubber bung and sealed with a coded aluminium cap. -Sealed cup of aluminium laminate containing the lyophilised product.

Presentations:

Boxes with vials each containing 1000, 2500, 5000 and 10000 doses Boxes with cups containing 1000, 2500, 5000 and 10000 doses.

Manufactured by:

Intervet International BV Boxmeer, The Netherlands.

Imported & Marketed by:

Intervet India Pvt Ltd. Sagar complex, Bldg.B-1, Gala No.12 to 16, Ovali Village, Bhiwandi, Thane 421302 India. Imp. Lic. No.: SV-6-597

