SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Ma5 + Clone 30 lyophilisate for oculonasal suspension/use in drinking water for chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	**per dose**
Live Infectious Bronchitis virus strain Ma5	≥ $10^{3.0}$ EID_{50*}
Live Newcastle Disease virus Clone 30	≥ $10^{6.0}$ ELD_{50**}

* egg infective dose 50%
** embryo lethal dose 50%

Excipients
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension / use in drinking water.

Vials: white/off-white coloured pellet.
Cups: white/off white, predominantly spherical shaped.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use specifying the target species

For the active immunisation of fowls against Massachusetts type or serologically related types of Infectious Bronchitis and against Newcastle Disease.
Duration of immunity: 6 weeks.

4.3 Contraindications

Only healthy birds should be vaccinated. Sick or weak birds will not develop adequate immunity following vaccination.

4.4 Special warnings for each target species

The vaccine viruses spread rapidly to susceptible chicks.

4.5 Special precautions for use

Special precautions for use in animals
A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration. Immuno-competence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress. Under certain conditions, for example extreme disease pressure and variant challenge, fully immune birds may succumb to disease. Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Newcastle Disease Virus can cause transitory conjunctivitis in man. It is recommended to wear respiratory and eye protection in compliance with current European standards.
For more information contact the manufacturer.
Hands should be washed and disinfected after vaccinating.

4.6 Adverse reactions (frequency and seriousness)

Slight respiratory reaction.

4.7 Use during pregnancy, lactation or lay

Vaccination during the laying period may be accompanied by a transient drop in egg production.

4.8 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. 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.

4.9 Amounts to be administered and administration route

The vaccine is administered by (coarse) spray, oculonasal use or in the drinking water. Administration by coarse spray or the oculonasal route is the method of choice when vaccinating young birds; fine spray for older birds.
The vaccine is safe to use from 1 day of age onwards.
The optimum time and method of administration depend largely on the local situation. Where necessary the advice of a veterinary surgeon should be sought.
The vaccine may be delivered as a freeze-dried cake in a glass vial or as freeze-dried spheres in cups. 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.

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.

Spray method

The vaccine should be dissolved in cool, clean water which is free of iron and chlorine. The appropriate number of vials should be opened under the surface of 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 volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds. This will vary according to the age of the birds being vaccinated and the management system. The vaccine medicated water should be spread evenly over the correct number of birds, at a distance of 30 - 40 cm. (12 - 16”), preferably when the birds are sitting together in dim light. The spray apparatus should be free from sediments, corrosion and traces of disinfectants (and ideally should be used for vaccination purposes only). Aerosol generators should be used only when it is known to be safe to the birds.

Number of doses	Day-old birds (Nozzle producing coarse droplets)	Older birds (Nozzle producing fine droplets)
1000	0.25 Litre	1 Litre

Oculonasal use

Dissolve the vaccine in Nobilis Diluent Oculo/Nasal or physiological saline solution (usually 30 ml per 1000 doses) and administer by means of a standardised dropper. One drop should be applied from a height of a few centimeter onto one nostril or eye. The handler should ensure that the nasal drop is inhaled by the bird.

Drinking water

The vaccine should be given in the early morning as 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 numbers of birds between standard dosages, the next higher dosage should be chosen.

The vaccine is presented in vials under vacuum. The vials should be opened under water or the content of the cup(s) should be poured into the water. Measure the correct volume of water for the number of birds to be vaccinated (see below), add 20 gram skimmed milk powder or 500 ml liquid skimmed milk per 10 litre, allow to stand for 15-30 minutes, then open the correct number of containers of vaccine under the surface of the water (vials) or into the water (cups). All containers used should be clean and free from any traces of detergent or disinfectant. In both cases mix the water containing the vaccine thoroughly with a clean stirrer, ensuring that all containers used are emptied. After reconstitution the suspension looks clear. Offer to birds immediately and ensure uptake of all the vaccine medicated water in 2 hours. Use clean cold water, in which chlorine or metals can neither be tasted nor smelled. Where water sanitisers are used consult Intervet technical staff. Only skimmed milk

should be used, as the fat in whole milk may block the automatic drinking systems as well as reduce vaccine virus efficacy.

Volumes of water for reconstitution of vaccine
The volume of water for reconstitution depends on the age of the birds and the management practice.

Simple drinking troughs and fountains
The following are guidelines:
1000 doses / litre/ age in days up to a volume of 20 litre per 1000 doses.
For heavy breeds, or in hot weather, the quantity of water may be increased up to 30 litre per 1000 doses. Where the number of birds is between the standard dosages, the next higher dosage should be used.

Nipple Drinkers
Drinker line management is known to have a significant effect on the viability of live vaccine virus. The vaccine virus can deteriorate very rapidly and it is essential to ensure that all birds received the correct dose.
Special care should be observed concerning the method of administration. For example, small header tanks may require recharging with medicated water several times during a 1 - 2 hour period.

Administration
Water should be withheld before vaccination. For recommendations see below under Management. Ensure that all medicated water is consumed within 1 - 2 hours. Turn on mains water when all the vaccine water has been consumed. Always make sure that there is food available when vaccinating.
Birds will not drink if they have no food to eat.

Management
Great care should be taken to ensure that all birds receive a full dose of vaccine when the product is administered in drinking water. When used in chickens where maternal antibody still exists, the way in which this vaccine is administered is critical.

The following points have been found to improve vaccine “take”:

1. Water withholding should be kept to a minimum, especially in broiler birds. Approximately half an hour is all that is required if the following management techniques are used.
2. Try to vaccinate at a time when birds are likely to be drinking, e.g. morning time for broilers, when food is in the food tracks.
3. Turn the lights down low when the water is turned off. For bell drinkers, go round the house emptying and cleaning the drinkers during the half-hour lights low period. Mix up the vaccine according to the recommendations, and towards the end of the half-hour water withholding period, go round all the drinkers filling each with water containing vaccine. Leave the house and turn the light up. The increased light intensity will stimulate the birds to look for water and food. Therefore, it is important that food is available or the birds will not be interested in drinking. In some cases, it helps to run food tracks at the time the light intensity is increased.

For nipple lines a substantial volume of residual water may remain in the lines after the half-hour water withholding/dark period. It is advisable to drain the lines and prime with vaccine loaded water before allowing the birds to have access to the drinker lines. Mix up the vaccine and apply to the header tank(s). Calculate the volume of water that is left in the tank below the outlet valve and make sure you add extra vaccine to this volume of water. For example, if 10 litre remain below the outlet pipe and you are using 10 litre/1000 birds to vaccinate, add one extra vial of vaccine when mixing up vaccine for that tank. The use of this extra vaccine is important.

4. Once the vaccine has been consumed, resume management practices as normal. This approach to vaccination will ensure a more even vaccination of the crop and will be less stressful to the birds. Performance should therefore be less adversely affected.

For further information on use of a vaccine in specific circumstances or in conjunction with other Intervet vaccines consult Intervet technical staff.

4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary

After administration of 100 doses only a slight reaction is observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATC vet code: QI01AD
Pharmacotherapeutic group: Immunologicals for aves, Domestic fowl, live viral vaccine.

Induction of active immunity of chickens, from one day-old onwards, against infectious bronchitis caused by Infectious Bronchitis Virus serotype Massachusetts and against infection with Newcastle Disease.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sorbitol
Hydrolysed gelatine
Pancreatic digest of casein
Disodium phosphate dihydrate
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal products.

6.3 Shelf life

Shelf life as packaged for sale (vials): 12 months (after pre-storage for 12 months at –25°C).
Shelf life as packaged for sale (cups): 24 months.
Shelf life after reconstitution
Vaccine medicated water should be used within 2 hours and not stored.

6.4 Special precautions for storage

Store at 2 °C - 8 °C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Sealed aluminium laminate cup with a polypropylene (cup) and polypropylene/polyethylene (lid) contact layer.

PET plastic box with 6 cups of 1000 doses
PET plastic box with 6 cups of 2500 doses
PET plastic box with 6 cups of 5000 doses
PET plastic box with 6 cups of 10 000 doses

PET plastic box with 12 cups of 1000 doses
PET plastic box with 12 cups of 2500 doses
PET plastic box with 12 cups of 5000 doses
PET plastic box with 12 cups of 10 000 doses

Carton containing 1 or 10 vials of hydrolytic type I glass containing a freeze-dried pellet. The vial is closed with a halogenobutyl rubber stopper and sealed with an aluminium cap.
Vials may contain 500, 1000, 2500, 5000 or 10,000 doses, but not all presentations may be marketed

6.6 Precautions for disposal of unused veterinary medicinal product or waste material derived from use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4117

9. DATE OF FIRST AUTORISATION

20 February 1997

10. DATE OF REVISION OF THE TEXT

November 2024

Approved 18 November 2024
Gavin Hall