

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB H120

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Live Avian Infectious Bronchitis virus strain IB H120

per dose

$\geq 3.0 \log_{10} \text{EID}_{50}$

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate for suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens

4.2 Indications for use, specifying the target species

For the active primary immunisation of chickens from day old, to reduce mortality and clinical signs resulting from infection with Infectious Bronchitis of the Massachusetts serotype.

Onset of immunity: at latest 3 weeks (based upon vaccination-challenge interval tested; this period may be shorter but this has not been investigated).

Duration of immunity: at least 6 weeks

4.3 Contraindications

Do not vaccinate unhealthy birds. Sick or weak birds will not develop adequate immunity following vaccination.

4.4 Special warnings for each target species

The vaccine virus may spread to unvaccinated birds. Primary vaccination of fully susceptible laying hens with Nobilis IB H120 might cause a slight fall in egg production. (see also section 4.7)

4.5 Special precautions for use

Special precautions for use in animals

In young birds the intensity of the reaction produced by the vaccine and also the degree of immunity will vary. This variation is related to the presence and amount of maternal antibodies to IB in the chicken and also the general health and condition of the birds. Thus, hygiene and management are particularly important in the post-vaccination period.

Antibiotic medication: When stocks are known to be infected with mycoplasma or there is a history of other infections, e.g. *E. coli*, it is suggested that antibiotics are administered to reduce the level of infection. The antibiotic manufacturers' recommendations should be followed at all times.

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. Immunocompetence 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, 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

Wash and disinfect hands after use.

When spraying the vaccine, to avoid hay-fever like reactions in some individuals, well fitting masks to appropriate EU standards or better and eye protection to appropriate EU standards must be worn by the operator and staff.

4.6 Adverse reactions (frequency and seriousness)

The reaction seen after primary vaccination is mild and takes the form of slight respiratory symptoms such as slight sneezing, mild coughs and mild gasping, 4-7 days later. These symptoms normally disappear within 2 weeks.

4.7 Use during pregnancy, lactation or lay

Under normal conditions, the vaccine is not recommended for use in laying birds.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with the live Newcastle disease (strain Clone 30 and C2) vaccines and live rhinotracheitis (strain 11/94) vaccines by Intervet.

Safety and efficacy data are available which demonstrate that Infectious bursal disease vaccine (strain D78) can be administered 7 days after the administration of Nobilis IB H120.

Vaccines which target non respiratory diseases (such as Marek's disease vaccines) may be administered with Nobilis IB H120 provided that each of the vaccines is administered using the recommended route and the recommended doses.

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.

4.9 Amounts to be administered and administration route

The vaccine can be administered to 1-day old chicks and older chickens by coarse spray or by the intranasal/ocular route of administration. The vaccine can be administered to 7-day and older chicks by drinking water.

Drinking water:

When administering the vaccine by drinking water use cool, clean water supplemented with 2 gram of skimmed milk powder or 50ml of liquid skimmed milk per liter to dissolve the vaccine, as it is known that this will make the virus retain its activity.

Reconstitution of vaccine:

The vaccine is presented in vials under vacuum. Measure the correct volume of water for the number of birds to be vaccinated (see below) and open the correct number of vials of vaccine under the surface of the water. All containers used should be clean and free from any traces of detergent or disinfectant. Mix thoroughly with a clean stirrer, ensuring that all vials used are emptied. Offer to birds immediately.

Use clean cold water, in which chlorine or metals can neither be tasted nor smelled. Where water sanitisers are used consult Intervet technical staff. Chlorine at levels as low as 1 ppm is known to have a detrimental effect on vaccine virus stability, therefore the use of liquid skimmed milk is recommended to prolong the life of the virus. This may be added to the water at the rate of 500 ml (approximately 1 pint) per 10 litres of water. After mixing well, the solution should be allowed to stand for 15-30 minutes before adding the vaccine. 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 per litre per age in days up to a volume of 20 litres per 1000 doses.

For heavy breeds, or in hot weather, the quantity of water may be increased up to 30 litres 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. The following points have been found to improve vaccine "take":

- 1 Water withholding should be kept to a minimum. 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. 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 litres remain below the outlet pipe and you are using 10 litres/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 and will be less stressful to the birds. Performance should therefore be less adversely affected.

Spray vaccination of day old chicks:

This technique has been developed for use in day-old birds, and is normally required for emergency use only. Only spray apparatus approved by Intervet should be used and it is advisable to consult the technical staff of the distributors before using this technique. The volume of water (see above) for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds, and will vary according to the age of the birds being vaccinated and the management system. The reconstituted vaccine should be spread evenly over the 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.

For further information on use of a vaccine in specific circumstances consult Intervet technical staff.

Eye- or nose-drop administration:

Reconstitute the vaccine with the appropriate amount of a suitable diluent and administer by means of the standardised dropper. One drop should be applied into one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird.

For eye- or nose-drop administration Nobilis Diluent Oculo Nasal (Vm 01708/4502, VPA 10996/203/1), is available in a dropper in two dosage forms (1000 and 2500 doses).

Vaccination programme

The optimal time and method of administration depend largely upon the local situation.

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

Similar effects to a single dose (see section 4.6)

4.11 Withdrawal Period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for aves, domestic fowl, live viral vaccines, avian infectious bronchitis virus.

ATC vet code : QI01AD07

To stimulate active immunity against Massachusetts type of Infectious Bronchitis virus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol,
Hydrolysed Gelatine,
Pancreatic digest of casein,
Di-sodium phosphate dihydrate
water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale

2 years

Shelf life after dilution or reconstitution according to directions

2 hours

6.4 Special precautions for storage

Store between +2°C and +8°C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 or 10 glass vials (10 ml) of type II or type I Ph.Eur. glass, closed with a halogenobutyl rubber stopper and sealed with a colour coded aluminium cap, containing 500, 1000, 2500, 5000 or 10,000 doses. Not all presentations may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/135/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th August 2010

10 DATE OF REVISION OF THE TEXT