

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis AE 1143

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Avian Encephalomyelitis virus (strain Calnek 1143) $\geq 10^{3.0}$ EID₅₀ per dose

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate for suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (breeding stock)

4.2 Indications for use, specifying the target species

For active immunisation of breeding chickens to reduce vertical transmission and the adverse effects on egg lay and hatchability due to Avian Encephalopathy and to induce passive immunity against infection with Avian Encephalomyelitis (Epidemic tremor) in the progeny in the critical first few weeks of their life.

Duration of active immunity: entire laying period

Onset of active immunity: 4 weeks

4.3 Contraindications

The vaccine virus has retained its full virulence and should therefore not be given to birds younger than 2 months of age or birds in lay.

4.4 Special warnings for each target species

Only healthy birds of at least 2 months of age should be vaccinated.

Vaccination of layers and breeding stock must be carried out at least one month before the beginning of the laying period, thus minimising the risk of A.E. in chickens hatched from the eggs of these birds.

Eggs from vaccinated birds should not be used for hatching for at least 1 month after vaccination.

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.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinated birds should be isolated from non-vaccinated birds since the vaccine virus can spread to non-vaccinated birds in particular chickens, pheasants, quail and turkeys.

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

Wash and disinfect hands after use.

Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Not to be used for birds in lay

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine 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 in the drinking water.

Birds should be vaccinated at 3-4 months of age and again at moulting, if appropriate.

Administration in drinking water:

Reconstitution of vaccine:

The vaccine is presented in vials under vacuum. Measure the correct volume of cool clean drinking 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 to be diluted in 20 litres.

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 1000 doses of extra 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.

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

No adverse effects at 10x dose.

4.11 Withdrawal Period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC code : QI01AD02

To stimulate active immunity in breeding chickens and provide passive immunity to their progeny against Avian Encephalomyelitis (Epidemic tremor).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Skimmed milk powder
Tryptose
Disodium edetate
Sodium ascorbate
Water for Injection

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 the directions: Vaccine medicated water should be used within 2 hours and not stored.

6.4 Special precautions for storage

Store in a refrigerator (2°C to 8 °C). Protect from light. Protect from frost.

6.5 Nature and composition of immediate packaging

Carton with 1 or 10 glass vials (type II or type I Ph. Eur.) containing 500, 1000 or 2500 doses, closed with a halogenobutyl rubber bung and sealed with a coded aluminium cap.

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
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Magna Business Park
Citywest Road
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8 MARKETING AUTHORISATION NUMBER(S)

VPA No. 10996/130/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th December 2009

10 DATE OF REVISION OF THE TEXT