Nobilis AE 1143 Data Sheet

Lyophilisate for suspension.

Presentation

Live freeze-dried v accine containing $\geq 10^{3.0}$ EID₅₀ live Avian Encephalomyelitis virus (strain Calnek 1143) per dose.

Uses

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 life.

<u>Duration of active immunity</u>: entire laying period.

Onset of active immunity: 4 weeks.

Dosage and administration

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:

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":

- 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.
- 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.

Contra-indications, warnings, etc.

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.

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 eggs of these birds.

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

After administration of a 10x overdose no adverse effects were reported.

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.

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.

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product. Do not mix with any other medicinal product.

Operator warning:

Wash and disinfect hands after use.

Withdrawal period:

Zero days.

FOR ANIMAL TREATMENT ONLY. KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Pharmaceutical precautions

Store between $+2^{\circ}$ C to $+8^{\circ}$ C. Protect from light. Do not freeze. Vaccine medicated water should be used within 2 hours and not stored.

Disposal advice:

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

Legal category POM-VPS

Package quantities

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 packs may be marketed.

Further information

Nil.

Marketing Authorisation number

Vm 01708/4281

Marketing Authorisation holder

Intervet UK Ltd Walton Manor, Walton Milton Keynes, Bucks MK7 7AJ

_

Distributed in Northern Ireland by:

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

Date of text preparation:

16 April 2008.