

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Gumboro 228E.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance: per dose (ml)
Live Gumboro virus strain 228E $\geq 2.0 \log_{10} \text{EID}_{50}^*$

* EID_{50} = Egg Infective dose 50%

Excipient(s)

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Powder for Oral Solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens from 10 days of age.

4.2 Indications for use, specifying the target species

For the active immunisation of chickens to reduce mortality, clinical signs and/or lesions of Infectious Bursal Disease (Gumboro) Infectious Bursal Disease (Gumboro disease).

Onset of immunity: Immunity develops within 7 days.

Duration of immunity: Data from the field shows that broilers are protected throughout the rearing period and breeder and layers birds are protected at least until the protection is boosted by use of an inactivated vaccine before the onset of lay.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The vaccine virus may spread and care should be taken to prevent spread of the vaccine strain to non-vaccinated birds.

4.5 Special precautions for use

Special precautions for use in animals

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

The properties of the vaccine virus are such that the virus may spread to in-contact birds. Care should be taken to ensure that the vaccine virus does not spread to unvaccinated birds.

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

Wash and disinfect hands after use.

4.6 Adverse reactions (frequency and seriousness)

The vaccine may cause a transient lymphocyte depletion in the bursa of Fabricius. This does not result in a significant immunosuppressive effect.

4.7 Use during pregnancy, lactation or lay

Do not use for birds in lay or within 4 weeks of the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

The vaccine is administered in the drinking water.

Vaccination programme

Birds, which should be at least 10 days of age, should be given a single vaccination. The optimum age for vaccination depends on the level of maternal antibody in the

chicks at day old, but normally lies in the range 10-18 days. For information on use of a vaccine in specific circumstances consult Intervet technical staff.

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.

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.

For reconstitution, 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.

Management

Great care should be taken to ensure that all birds receive a full dose of vaccine when the product is administered. 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 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 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 consult Intervet technical staff.

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

No particular symptoms at ten times dose.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals, immunologicals for aves, domestic fowl, live viral vaccines, avian infectious bursal disease virus (gumboro disease).

ATC vet code: QI01AD09

The active ingredient is Gumboro disease virus strain 228E, which stimulates active immunity against Infectious Bursal disease (Gumboro) in the birds receiving it.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Bovine Serum Albumin
Potassium Phosphate
Disodium Phosphate Dihydrate
Monosodium glutamate

6.2 Major 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 reconstitution according to directions: 2 hours

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Vials of Type I Ph.Eur. glass, closed with a nitril rubber stopper and sealed with a colour coded aluminium cap.

Cartons with 1 or 10 vials containing 500, 1000, 2500, 5000 or 10,000 doses of vaccine.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

VPA10996/134/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd September 2011

10 DATE OF REVISION OF THE TEXT

April 2018