1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Gumboro 228E lyophilisate for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of reconstituted vaccine:

Active substance:
Live infectious bursal disease virus (IBDV), strain 228E 2.0-3.0 $\log_{10}$ EID_{50}

Excipients:

Qualitative composition of excipients and other constituents
Sucrose
Bovine Serum Albumin
Potassium Phosphate
Disodium Phosphate Dihydrate
Monosodium glutamate
Water for injections

Lyophilisate
Vials: light brown/reddish brown-coloured pellet.
Cups: light brown/reddish brown, predominantly sphere shaped.

3. CLINICAL INFORMATION

3.1 Target species

Chickens from 10 days of age.

3.2 Indications for use for each target species

For the active immunisation of chickens to reduce mortality, clinical signs and/or lesions of 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Chickens:

Undetermined frequency (cannot be estimated from the available data)	Bursa of Fabricius lymphocyte depletion[1]

[1] Transient. Does not result in a significant immunosuppressive effect.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

3.8 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.

3.9 Administration routes and dosage

In drinking water use.

Dosage:
2.0-3.0 $\log_{10}$ EID_{50} per animal via drinking water application.

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.

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 latter presentation the cups may contain 3 up to 400 spheres depending on the required dosages and production yields. In case of the veterinary medicinal product presented in cups, do not use the veterinary medicinal product if the contents 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.

Reconstitution of vaccine: The vaccine is presented in vials under vacuum or as freeze-dried spheres in cups. For reconstitution, the vials should be opened under water or the content of the cup(s) should be poured into a small volume of water. In both cases mix the water containing the vaccine well before use. After reconstitution the suspension looks clear.
Mix the reconstituted suspension with the correct volume of water for the number of birds to be vaccinated (see below). All containers used should be clean and free from any traces of detergent or disinfectant. Mix thoroughly with a clean stirrer. Offer to birds immediately.
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.

<u>Simple drinking troughs and fountains</u>
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.

<u>Nipple Drinkers</u>:
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 veterinary medicinal 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.
4. 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.
5. 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No particular symptoms at ten times dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Vial of hydrolytical type I glass (Ph. Eur.) containing the freeze-dried vaccine pellet.
Contents and presentation: 500, 1000, 2500, 5000 or 10000 doses per vial in packs of 10 vials. The vials are closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.
Sealed aluminium laminate cup with a polypropylene (cup) and polypropylene/polyethylene (lid) contact layer.
Pack sizes presentation in cups:
PET plastic box with 12 cups of 1,000 doses, 2500 doses, 5000 doses or 10000 doses.

PET plastic box with 6 cups of 10,000 doses.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/134/001

8. DATE OF FIRST AUTHORISATION

12/11/2004

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

02/10/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).