SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF PRODUCT

Active ingredient	**per dose**
Live IBDV strain 228E	2 - 3 $\log_{10}$ EID_{50} *

* egg infective dose

Excipients
For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water.

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

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use specifying the target species

For the active immunisation of chickens against Infectious Bursal Disease (Gumboro).

4.3 Contraindications

The vaccine should not be used in birds without maternally derived antibodies. Spread of the vaccine strain to such birds should be prevented.

4.4 Special warnings for target species

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 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.

4.5 Special precautions for use

Special precautions for use in animals
Only healthy birds should be vaccinated.

Special safety precautions to be taken by persons administering the product
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 when used in chickens with maternally derived antibodies (MDA).

4.7 Use during pregnancy, lactation or lay

Do not vaccinate birds in lay.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

The vaccine is administered in the drinking water.

Reconstitution of vaccine
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 product presented in cups, do not use the 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.

The vials should be opened under water or the content of the cup(s) should be poured into the water. In both cases mix the water containing the vaccine well before use. After reconstitution the suspension looks clear. Measure 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, ensuring that all vials used are emptied. 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 litre 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 litre per 1000 doses.
For heavy breeds, or in hot weather, the quantity of water may be increased up to 30 litre 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.

Vaccination programme
Birds, which should be at least 10 days of age, should be given a single vaccination. The optimum age for vaccination may be calculated using the level of maternal antibody in the chicks at day old (Kouwenhovens formula), but normally lies in the range 12 - 18 days. Further information is available from Intervet technical staff.

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. 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 litre remain below the outlet pipe and you are using 10 litre/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.

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

No particular symptoms at ten times dose.

4.11 Withdrawal period

Zero days.

5. PHARMACOLOGICAL PROPERTIES

The active ingredient is living Gumboro disease virus strain 228E which stimulates active immunity against Infectious Bursal disease (Gumboro) in the birds receiving it.
ATC code QI01AD09

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stabiliser, buffer

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Lyophilisate pellet in glass vials: 24 months at -20°C (storage manufacturer), followed by 24 months at 2-8°C.
Lyophilisate spheres in cups: 24 months at 2-8°C.

Shelf life after reconstitution according to the directions: 2 hours

6.4 Special precautions for storage:

Store at 2 °C - 8 °C. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard boxes containing 1 or 10 glass vials of hydrolytic (type I Ph.Eur.), closed with a halogenobutyl rubber stopper and sealed with a colour coded aluminium cap.
Vials contain 500, 1000, 2500, 5000 or 10,000 doses of vaccine.
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
PET plastic box with 12 cups of 2,500 doses
PET plastic box with 12 cups of 5,000 doses
PET plastic box with 12 cups of 10,000 doses
PET plastic box with 6 cups of 10,000 doses
Not all presentations may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4120

9. DATE OF FIRST AUTHORISATION

04 April 1997

10. DATE OF REVISION OF THE TEXT

November 2024

Approved 14 November 2024
Gavin Hall