# 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Gumboro D78 live

# 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active substance:**            **per dose**
Gumboro disease virus (strain D78)    $\geq 10^{4.0}$ TCID$_{50}$

**Excipients:**
For a full list of excipients see section 6.1.

# 3 PHARMACEUTICAL FORM

Lyophilisate for suspension

# 4 CLINICAL PARTICULARS

## 4.1 Target Species

Chickens from 14 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).
Onset of immunity: 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

It is only necessary to apply the vaccine once to susceptible birds and this should be done as early as possible from 14 days of age. In the field, maternal antibodies will exist in the majority of chicks, therefore vaccination before 17 days for broiler-type birds and 21 days for replacement layers is not normally recommended where parent birds have been injected with an inactivated Gumboro vaccine.

The properties of D78 are such that the vaccine virus will spread to in-contact birds and vaccine virus may increase in virulence on bird to bird passage.

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.

## 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.

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.

## 4.6 Adverse reactions (frequency and seriousness)

None

## 4.7 Use during pregnancy, lactation or lay

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

## 4.8 Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are available which demonstrate that this vaccine can be administered after at least 7 days after the administration of the Intervet live Newcastle disease vaccine and the live infectious bronchitis (strain H120) vaccine Nobilis ND Clone 30 and Nobilis IB H120. The 7 days are based on the data presented by the applicant in the marketing authorisation file. They correspond to the minimum time between administrations for which compatibility data have been submitted.

**4.9 Amounts to be administered and administration route**

The vaccine is administered in the drinking water.

**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.
Use clean cold water, in which chlorine or metals can neither be tasted nor smelt. 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.

**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 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 or in conjunction with other Intervet vaccines consult Intervet technical staff.

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

None

**4.11 Withdrawal period(s)**

Zero days

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

The vaccine contains live Infectious Bursal (Gumboro) Disease virus strain D78, for administration to chickens to stimulate active immunity against the disease.
ATCvet code: QI01AD09

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Sucrose
Bovine Serum Albumin
Potassium dihydrogen phosphate
di-Sodium hydrogen phosphate
Monosodium glutamate
Water for injections

**6.2 Major incompatibilities**

Do not mix with any other medicinal product.

**6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 15 months.
Shelf-life after incorporation into drinking water: 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

Carton containing one or ten type I (Ph.Eur) glass vials with 1000, 2500, 5000 or 10,000 doses closed with rubber stoppers and sealed with a colour coded aluminium cap.
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 in accordance with national requirements.

## 7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/133/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd April 2008

## 10 DATE OF REVISION OF THE TEXT

April 2018