SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Gumboro D78 lyophilisate for oculonasal suspension/use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance:
Infectious bursal disease virus (IBDV) (Gumboro disease virus, GDV), strain D78, Live: ≥ 4.0 $\log_{10}$ $TCID_{50}$

$TCID_{50}$ = Tissue culture infective dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Sucrose
Bovine serum albumin
Monobasic potassium phosphate
Disodium phosphate dihydrate
Monosodium glutamate
Water for injections

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

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

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

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. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.
Care should be taken to ensure that the vaccine virus does not spread to unvaccinated birds.
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.

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

3.6 Adverse events

Chickens:
None known.

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 its local representative 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:
Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

Complete lack of immunosuppression has not been demonstrated.

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

At least 4.0 $\log_{10}$ $TCID_{50}$ per animal in drinking water, spray or oculo-nasal use.
The volume used for application depends on the way of administration.

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 100 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.

Reconstitution of vaccine

A. Drinking water
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. The vaccine should be dissolved in cool, clean water which is free of iron and chlorine. By adding 2 grams of skimmed milk powder per litre of water the virus retains its activity much longer. Ensure uptake of all the vaccine-medicated water in 2 hours.
Depending on the weather conditions, it may be advisable to deprive the birds of water prior to vaccination. A sufficient number of water containers to provide adequate drinking space is essential. These should be clean and free from traces of detergents and disinfectants. Dissolve 1000 doses in as many litres of water as the age of the birds in days, to a maximum of 40 litres.
The vaccine should be given in the early morning as this is the main period of drinking or the cool period on a hot day. When vaccinating larger flocks, it is advisable to start by dissolving only part of the vaccine. If vaccine is administered through a central water supply or a proportioner, great care should be taken. For numbers of birds between standard dosages, the next higher dosage should be chosen.

B. Spray method
Reconstitute the vaccine in cool, clean water, to which 2% skimmed milk may be added. The vials should be opened under water or the content of the cup(s) should be poured into water. Chlorinated water should not be used. In both cases mix the water containing vaccine well before use. After reconstitution the suspension looks clear. The water and spray apparatus should be free from sediments, corrosion and traces of disinfectants or antiseptics. Ideally the apparatus should be used for vaccination purposes only. The volume of diluent for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds. This will vary according to the age of the birds being vaccinated and the management system, but a quantity of 1000 doses per litre of water is suggested. The vaccine suspension should be sprayed evenly over the birds at a distance of 30-40 cm, preferably when the birds are sitting together in dim light. If applicable, reduce or stop ventilation to prevent loss of spray.

C. Oculonasal use
The vaccine should be dissolved in physiological saline solution (usually 30 ml per 1000 doses) and administered by means of a standardised dropper (of which the droplet size is known and consistent). The amount of diluent required for eye- or nose-drop administration depends on the number of doses and the droplet size. One drop should be applied from a height of a few centimetres onto one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the bird.

Wash and disinfect hands and equipment after vaccinating. Any surplus vaccine should be destroyed by burning or by boiling.

Each container should be used immediately after opening.

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.

Vaccination programmes
It is only necessary to apply the vaccine once to susceptible birds and this should be done as early as possible. 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.

Suggested vaccination programmes
This programme is intended only as a guide; local conditions must be allowed for.

Broilers	Rearing pullets and breeding stock
17 days old*	21 days old
21 - 24 days old	28 - 30 days old
28 - 30 days old	

*This may be reduced to 14 days if MDA is known to be present at only very low levels.

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 MSD vaccines consult marketing authorisation holder's technical staff.

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

No symptoms.

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 vaccine contains live Infectious Bursal (Gumboro) Disease virus for administration to chickens to stimulate active immunity against the disease.

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: 15 months
(after max 2 years at –25 ºC).
Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Cardboard box containing 1 or 10 glass vials of hydrolytic type I vials with 1 000, 2 000, 2 500, 3 000, 5 000 and 10 000 doses. The vials are closed with rubber stoppers and sealed with a colour coded aluminium cap.
Sealed aluminium laminate cup with a polypropylene (cup) and polypropylene/polyethylene (lid) contact layer.

Pack sizes:
Cardboard box with vials of 1 or 10 x 1 000 doses, 2 000 doses, 2 500 doses, 3 000 doses, 5 000 doses or 10 000 doses.
PET plastic box with 12 cups of 1 000 doses, 2 500 doses, 5 000 doses and 10 000 doses.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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 International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4121

8. DATE OF FIRST AUTHORISATION

15 February 1994

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

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk

Gavin Hall
Approved: 22 December 2025