

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box vials
PET PLASTIC BOX Cup

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCE

Infectious bursal disease virus (IBDV) (Gumboro Disease virus, GDV), strain D78,
Live: $\geq 4.0 \log_{10}$ TCID₅₀/dose

3. PACKAGE SIZE

1 000 doses
2 000 doses
2 500 doses
3 000 doses
5 000 doses
10 000 doses
10 x 1 000 doses
10 x 2 000 doses
10 x 2 500 doses
10 x 3 000 doses
10 x 5 000 doses
10 x 10 000 doses
12 x 1 000 doses
12 x 2 500 doses
12 x 5 000 doses
12 x 10 000 doses

4. TARGET SPECIES

Chickens.

6. ROUTES OF ADMINISTRATION

Oculonasal use (incl. spray) or drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.
Keep container in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

Intervet International B.V.

Distributor in Northern Ireland:

Intervet Ireland Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/4121

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS Label – Lyophilisate vials**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Gumboro D78



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Live IBDV, D78

1 000 doses
2 000 doses
2 500 doses
3 000 doses
5 000 doses
10 000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS Label - Lyophilisate Cups**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Gumboro D78



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 000 doses (3-100 spheres)
2 500 doses (3-100 spheres)
5 000 doses (3-100 spheres)
10 000 doses (3-100 spheres)

Live IBDV, D78

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each dose of reconstituted vaccine contains:

Active substance:

Infectious bursal disease virus (IBDV) (Gumboro disease virus, GDV), strain D78,
Live: $\geq 4.0 \log_{10} \text{TCID}_{50}$

TCID_{50} = Tissue culture infective dose 50%

Lyophilisate:

Vials: light brown/reddish brown-coloured pellet.

Cups: light brown/reddish brown, predominantly spherical shaped.

3. Target species

Chickens.

4. Indications for use

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

5. Contraindications

None.

6. Special warnings

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.

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.

Laying birds:

Not applicable

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.

Overdose:

No symptoms.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

At least 4.0 log₁₀ TCID₅₀ per animal in drinking water, spray or oculonasal use. The volume used for application depends on the way of administration.

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.

9. Advice on correct administration

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.

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 spread as a coarse spray evenly over the birds at a distance of 30 to 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.

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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Protect from light.

Keep the container in the outer carton.

Shelf life after reconstitution according to the directions: 2 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/4121

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder:

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

Netherlands

Manufacturer responsible for batch release:

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

Local representative:

MSD Animal Health UK Limited.
Walton Manor, Walton
Milton Keynes, MK7 7AJ, United Kingdom

Contact details to report suspected adverse reactions:

UK(GB)

MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

UK(NI)

Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

Distributor in Northern Ireland:

Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24, Ireland

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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

POM- Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 22 December 2025