

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**{Carton box (vials)**  
**PET PLASTIC BOX (CUPS) }**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Live IBVD strain D78 at least 4,0 log<sub>10</sub> TCID<sub>50</sub>/dose

**3. PHARMACEUTICAL FORM**

Lyophilisate for oculonasal suspension / use in drinking water

**4. PACKAGE SIZE**

500 doses  
1000 doses  
2000 doses  
2500 doses  
3000 doses  
5000 doses  
10 000 doses  
12 x 1000 doses  
12 x 2500 doses  
12 x 5000 doses  
12 x 10 000 doses

**5. TARGET SPECIES**

Target species: Chickens.

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For oculonasal, spray or drinking water administration. Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

## 10. EXPIRY DATE

Expiry end of: {month/year}  
Once reconstituted use within 2 hours.

## 11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.  
Protect from light.  
Keep container in the outer carton.

## 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

For animal treatment only.  
To be supplied only on veterinary prescription.

POM-V

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

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

### MA Holder:

MSD Animal Health UK Ltd. Walton Manor, Walton Milton Keynes MK7 7AJ

### Distributor in Northern Ireland:

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

## 16. MARKETING AUTHORISATION NUMBER

Vm 01708/4237

## 17. MANUFACTURER’S BATCH NUMBER

Lot: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS {Label (Vials) }**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Live IBVD strain D78 at least 4,0 log<sub>10</sub> TCID<sub>50</sub>/dose

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

1000 doses.

**4. ROUTE(S) OF ADMINISTRATION**

Route: oral administration.

**5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Batch: {number}

**7. EXPIRY DATE**

Expiry end of: {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

POM-V

Vm 01708/4237

Read package leaflet before use.

Target species: Chickens.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**LABEL – Lyophilisate CUPS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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



**2. QUANTITY OF ACTIVE SUBSTANCE**

Live IBDV, D78

**3. CONTENTS BY WEIGHT, BY VOLUME OR NUMBER OF DOSES**

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

**4. ROUTE(S) OF ADMINISTRATION**

See package leaflet.

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER.**

Lot

**7. EXPIRY DATE**

EXP

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**PACKAGE LEAFLET FOR:**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder  
MSD Animal Health UK Limited  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

Manufacturer for the batch release  
Intervet International B.V.  
Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

Content per dose:

Live Gumboro disease virus strain D78  $\geq 10^{4.0}$  TCID<sub>50</sub>\*

\*Tissue culture infective dose 50%

Lyophilisate for ocular nasal suspension/use in drinking water.

Vials: light brown/reddish brown-coloured pellet.

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

**4. INDICATION(S)**

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

**5. CONTRAINDICATIONS**

Do not use in unhealthy birds. Sick or weak birds will not develop adequate immunity following vaccination.

**6. ADVERSE REACTIONS**

None.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Chickens.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The vaccine is administered in the drinking water.

*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

At least 4.0 log<sub>10</sub> TCID<sub>50</sub> per animal by drinking water, spray or oculo/nasal instillation.

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.

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.

#### 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 gram skimmed milk powder per litre 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 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. Intranasal / intra-ocular instillation

The vaccine should be dissolved in physiological saline solution (usually 30 ml per 1000 doses) and administered by means of a standardized 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 liter remain below the outlet pipe and you are using 10 liter/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 MSD technical staff.

## **10. WITHDRAWAL PERIOD(S)**

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 after the expiry date stated on the label and carton.

## **12. SPECIAL WARNING(S)**

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 warnings for each target species:**

Vaccinate healthy animals only.

**Special precautions for use in animals**

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 product to animals**

Wash and disinfect hands after use.

**Interactions**

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.

Do not mix with any other veterinary medicinal product.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

October 2021

**15. OTHER INFORMATION**

For animal treatment only.

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

**Pack sizes**

Cardboard box containing 1 or 10 hydrolytic glass vials type I (Ph.Eur) vials with 1000, 2000, 2500, 3000, 5000 or 10000 doses.

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  
Not all presentation may be marketed.  
Not all pack sizes may be marketed.

**MA number:** Vm 01708/4237

**Legal category**

POM-V

To be supplied only on veterinary prescription.

**Distributor in Northern Ireland:**

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

Approved: 27/10/21

