

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON BOX (VIALS)
PET PLASTIC BOX (CUPS)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live IBDV strain 228E 2.0-3.0 log₁₀ EID₅₀/dose

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water

4. PACKAGE SIZE

10 x 500 doses
10 x 1000 doses
10 x 2000 doses
10 x 2500 doses
10 x 3000 doses
10 x 5000 doses
10 x 10000 doses
6 x 10000 doses
12 x 10000 doses
12 x 2500 doses
12 x 5000 doses
12 x 10000 doses

5. TARGET SPECIES

Target species: Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water 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. Do not freeze. 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.

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 Limited, 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 01708/4333

17. MANUFACTURER’S BATCH NUMBER

Lot: {number}
To be supplied only on veterinary prescription.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS Label GLASS VIALS**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live IBDV strain 228E 2.0-3.0 log₁₀ EID₅₀/dose

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

500 doses
1000 doses
2500 doses
5000 doses
10,000 doses

4. ROUTE(S) OF ADMINISTRATION

Route: oral administration.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP end of: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MA holder

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

Read the package leaflet before use.

Shelf life after reconstitution: 2 hours.

Vm 01708/4333

POM-V

Labelling – Minimum particulars to appear on the small immediate packaging units

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – Lyophilisate CUPS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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



2. QUANTITY OF ACTIVE SUBSTANCE

Live IBDV, 228E

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 (3-400 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:

Nobilis Gumboro 228E

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, Bucks, 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 228E
lyophilisate for use in drinking water for chickens.

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

Per dose of reconstituted vaccine:

Active substance:

Live IBD virus, strain 228E 2.0-3.0 log₁₀ EID₅₀

Lyophilisate for 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).

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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). 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. 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.

9. ADVICE ON CORRECT ADMINISTRATION

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) 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. 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 liter 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 liter per age in days up to a volume of 20 liter per 1000 doses. For heavy breeds, or in hot weather, the quantity of water

may be increased up to 30 liter 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.

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.

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.

Shelf life after reconstitution according to the directions: 2 hours. Do not use after the expiry date stated on the label and carton.

Keep container in the outer 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. 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 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.

Use during lay

Do not vaccinate birds in lay.

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. Do not mix with any other veterinary medicinal product.

Overdose

No particular symptoms were observed at ten times the single dose.

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

December 2021

15. OTHER INFORMATION

For animal treatment only.

Cardboard boxes containing 1 or 10 hydrolytic glass vials (type I Ph.Eur.) with 500, 1000, 2500, 5000 or 10,000 doses of vaccine.

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 pack sizes may be marketed.

MA number:

Vm 01708/4333

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 24

Approved 28 January 2022

A handwritten signature in black ink, appearing to read "A. Hunter.", positioned below the approval date.