

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Gumboro D78 live

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF PRODUCT

Active ingredient	per dose
Gumboro disease virus (strain D78)	$\geq 4.0 \log_{10} \text{TCID}_{50}$.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for oral administration.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use specifying the target species

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

4.3 Contra-indications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interaction with other medicinal products and other forms of interactions

Complete lack of immunosuppression has not been demonstrated. No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

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 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.

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 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 Intervet vaccines consult Intervet technical staff.

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

No specific treatment or antidote recommended.

4.11 Withdrawal periods

Zero days

5. IMMUNOLOGICAL PROPERTIES

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

ATC Vet code: QI01AD09

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stabiliser, buffer

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 at +2°C to +8°C (after max 2 years at –25°C)

Shelf life after dilution or reconstitution according to the directive

Vaccine medicated water should be used within 2 hours and not stored.

6.4 Special precautions for storage

Store at +2°C to +8°C. Do not freeze. Store out of light.

6.5 Nature and composition of immediate packaging

Cardboard box containing 1 or 10 glass type III (Ph.Eur) vials with 1000, 2000, 2500, 3000, 5000 and 10000 doses. The vials are closed with rubber stoppers and sealed with a colour coded aluminium cap. Not all presentation may be marketed.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. **MARKETING AUTHORISATION HOLDER**

Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Bucks. MK7 7AJ

8. **MARKETING AUTHORISATION NUMBERS**

Vm 01708/4237

9. **DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION**

15th February 1994

4th June 2004

10. **DATE OF REVISION SPC OF THE TEXT**

08/06/07

PROHIBITION OF SALE, SUPPLY AND /OR USE

Not applicable

Nobilis® GUMBORO D78



FOR ANIMAL TREATMENT ONLY



COMPOSITION

Nobilis Gumboro D78 is a live, freeze-dried vaccine against Infectious bursal disease (Gumboro). Each dose contains at least $4,0 \log_{10}$ TCID₅₀ of the Gumboro strain D78. The vaccine pellet contains stabilizers and gentamicin.

INDICATION

Immunization of chickens against Gumboro Disease.

ADMINISTRATION

A. Drinking water

The vaccine should be dissolved in an amount of water which will be consumed by the animals with approx. 2 hours.

B. Spray method

The vaccine should be dissolved in water in a quantity of 1000 doses per liter. It should be spread as a coarse spray evenly over the birds at a distance of 30 to 40 cm.

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. One drop should be applied from a height of a few centimeters onto one nostril or one eye.

Note: An Intervet oculo/nasal diluent is commercially available in several countries.

VACCINATION PROGRAMME

Nobilis Gumboro D78 can be administered to birds at 8-28 days of age by drinking water. Strain D78 is effective in the face of the maternally derived antibody level usually existing in flocks at 8-28 days of age. The optimal time of vaccination depends on the height of the maternally derived antibody level. In case the antibody level is very variable it is advised to vaccinate the chickens twice with an interval of one week.

Nobilis Gumboro D78 can also be safely administered at one day of age by eye drop and spray to birds with no or a low level of maternal antibodies. Alternatively birds with no maternal antibodies can be vaccinated with Nobilis Gumboro PBG98 at day-old.

IMMUNITY

The first signs of the antibody response were observed within one week after the vaccination.

VACCINATION REACTION

Postvaccination reactions have not been observed after vaccination of healthy chickens.

WITHDRAWAL PERIOD: none

PRECAUTIONS

- Wash and disinfect hands and equipment after vaccinating. Any surplus vaccine should be destroyed by burning or by boiling.
- Vaccinate healthy animals only.
- Each container should be used immediately and completely after opening.

STORAGE CONDITIONS

Store in a dark place at between 2° and 8°C.

PRESENTATIONS

Vials of 500, 1000, 2000, 2500, 3000, 5000 or 10 000 doses in packages of 10 vials.

Cups containing 1000, 2500, 5000, 10 000 or 25 000 doses in packages of 1, 10 or 50 cups.



Nobilis® GUMBORO D78

USO VETERINARIO

COMPOSICIÓN

Nobilis Gumboro D78 es una vacuna viva, liofilizada contra la enfermedad infecciosa de la bursa (Gumboro). Cada dosis contiene como mínimo $4,0 \log_{10}$ DLE₅₀ de la cepa de Gumboro D78. El liofilizado contiene estabilizantes y gentamicina.

INDICACIONES

Inmunización de pollos contra la enfermedad de Gumboro.

ADMINISTRACIÓN

A. Agua de bebida

La vacuna debe disolverse en una cantidad de agua igual a la que consumirán los animales en aproximadamente 2 horas.

B. Método en spray

La vacuna debe disolverse en agua en una cantidad de 1.000 dosis por litro. Debe diseminarse uniformemente entre las aves en forma de spray de gota gruesa a una distancia de 30 a 40 cm.

C. Instilación intranasal/intraocular

La vacuna debe disolverse en solución salina fisiológica (normalmente 30 ml por 1.000 dosis) y administrarse con un gotero estandarizado. Debe aplicarse una gota desde una altura de varios centímetros en un orificio nasal o en un ojo.

Nota: Diversos países disponen de un diluyente óculo/nasal Intervet comercial.

PAUTAS DE VACUNACIÓN

Nobilis Gumboro D78 puede administrarse a aves de 8-28 días de edad en el agua de bebida. La cepa D78 es efectiva ante el nivel de anticuerpos maternos que normalmente existe en crías de 8-28 días de vida. El momento óptimo de la vacunación depende del nivel alcanzado por los anticuerpos maternos. En caso de que el nivel de anticuerpos varíe mucho se aconseja vacunar a los pollos dos veces, con un intervalo de una semana.

Nobilis Gumboro D78 puede también ser administrado en forma segura al día de edad por medio de gota en el ojo y spray a aves sin o con bajos niveles de anticuerpos maternos.

Por otra parte, las aves sin anticuerpos maternos pueden vacunarse con Nobilis Gumboro PBG98 el primer día de vida.

INMUNIZACIÓN

Los primeros síntomas de respuesta de anticuerpos se observan en la primera semana después de la vacunación.

EFFECTOS SECUNDARIOS

No se han observado reacciones tras la vacunación de pollos sanos.

PERÍODO DE SUPRESIÓN

Ninguno.

PRECAUCIONES

- Lavar y desinfectar las manos y el material después de la vacunación. Destruir los restos de vacuna no usada mediante incineración o ebullición.
- Vacunar sólo animales sanos.
- Todo el contenido debe de ser utilizado en forma inmediata y completamente después de ser abierto

CONDICIONES DE CONSERVACIÓN

Conservar entre 2° y 8°C, en lugar oscuro.

PRESENTATIONS

Viales con 500, 1000, 2000, 2500, 3000, 5000 o 10 000 dosis en empaques de 10 viales.

Contenedores con 1000, 2500, 5000, 10 000 o 25.000 dosis en empaques con 1, 10 o 50 contenedores.

Importado y distribuido por Intervet S.A. Av. Los Frutales 245, Cuarto Piso, ATE, Lima 03 RUC: 20372399687

Venta bajo receta.

Reg. SENASA: B.01.1.01.I.450

Manténgase fuera del alcance de los niños.

Bolivia Reg. SENASAG PUV-B 000107/02

Importado y distribuido por Intervet Ecuador S.A. - Guayaquil

4A-1928-AGROCALIDAD

Importado y distribuido en Venezuela por: Intervet Venezolana S.A. RIF J-30327783-7

Registro MAS-SASA B.I 2.579

CPE 0608151918 Solo para uso Veterinario

Venta Bajo Prescripción del Médico Veterinario

Asesor Técnico: M.V. Alba Codutti



Nobilis® GUMBORO D78

FÜR TIERE

ZUSAMMENSETZUNG

Beim Nobilis Gumboro D78 handelt es sich um einen gefriergetrockneten Lebend-Impfstoff gegen infektiöse Bursitis (Gumboro-Krankheit). Jede Dosis enthält mindestens 4,0 log10 TCID50 des Gumboro-Stamms D78.

Der Impfstoff enthält Stabilisatoren sowie Gentamicin.

INDIKATION

Immunisierung von Hühnern gegen Gumboro-Krankheit.

GEBRAUCHSANWEISUNG

- A. Mit dem Trinkwasser
Der Impfstoff ist in soviel Wasser zu lösen, wie von den Tieren in ungefähr 2 Stunden aufgenommen wird.
- B. Sprühverfahren
Der Impfstoff ist in einer Menge von 1000 Dosen pro Liter in Wasser zu lösen und in Form eines groben Sprühnebels im Abstand von 30 bis 40 cm gleichmäßig über das Geflügel zu zerstäuben.
- C. Einträufeln in die Nase bzw. Augen
Der Impfstoff ist in physiologischer Kochsalzlösung zu lösen (normalerweise 30 ml pro 1000 Dosen) und mittels eines standardisierten Tropfers zu verabreichen. Ein Tropfen ist aus einer Höhe von einigen Zentimetern auf ein Nasenloch bzw. Auge zu verabreichen.
- Zur Beachtung:** In verschiedenen Ländern ist ein Intervet-Verdünnungsmittel für Augen- bzw. Nasenarzneimittel erhältlich.

IMPFPLAN

Nobilis Gumboro D78 kann an Vögel in einem Alter von 8-28 Tagen über das Trinkwasser verabreicht werden. Der Stamm D78 wirkt angesichts des üblicherweise bei Geflügel im Alter von 8 bis 28 Tagen vorkommenden, von der Mutter stammenden Antikörperspiegels. Der optimale Impfzeitpunkt hängt von der Höhe des von der Mutter stammenden Antikörperspiegels ab. Schwankt der Antikörperspiegel stark, so wird empfohlen, die Hühner zweimal im Abstand von einer Woche zu impfen.

Nobilis Gumboro D78 kann auch ab einem Alter von einem Tag mittels oculo-nasaler Instillation oder als Spray an Vögel ohne oder mit nur geringen maternalen Antikörperspiegeln verabreicht werden. Es ist jedoch auch möglich, Geflügel im Alter von einem Tag, die über keine mütterlichen Antikörper verfügen, mit Nobilis Gumboro PBG98 zu impfen.

IMMUNITÄT

Die ersten Zeichen von Antikörperbildung wurden innerhalb einer Woche nach der Impfung beobachtet.

IMPFREAKTION

Bei gesunden Hühnern wurden keine Nachreaktionen nach der Impfung beobachtet.

WARTEZEIT:

Keine

VORSICHTSMASSNAHMEN

- Hände und Geräte nach Durchführung der Impfung waschen und desinfizieren.
- Impfstoffreste sind durch Verbrennen oder Kochen zu zerstören.
- Nur gesunde Tiere impfen.
- Jedes Behältnis sollte nach Öffnung unmittelbar und vollständig aufgebraucht werden.

AUFBEWAHRUNG

Zwischen 2° und 8°C im Dunkeln aufbewahren.

PRESENTATIONS

Fläschchen mit 500, 1000, 2000, 2500, 3000, 5000 oder 10 000 Dosen, abgepackt zu jeweils 10 Fläschchen.

Jeder Becher enthält 1000, 2500, 5000, 10 000 oder 25 000 Dosen, verpackt zu jeweils 1, 10 oder 50 Bechern.



Nobilis® GUMBORO D78

USAGE VETERINAIRE

COMPOSITION

Le vaccin Nobilis Gumboro D78 est un vaccin vivant lyophilisé contre la maladie de Gumboro. Chaque dose contient au moins 4,0 log10 TCID50 de la souche de Gumboro D78. Le vaccin contient des stabilisateurs et de la gentamicine.

INDICATION

Immunisation de poulets contre la maladie de Gumboro.

ADMINISTRATION

- A. Eau de boisson
Le vaccin doit être dissous dans une quantité d'eau qui sera consommée par les animaux approximativement en moins de 2 heures.
- B. Nebulisation
Le vaccin doit être dissous dans de l'eau à raison de 1000 doses par litre. Il doit être distribué sous forme de spray grossier uniformément sur les oiseaux à une distance de 30 à 40 cm.
- C. Instillation intra-nasale/intra-oculaire.
Le vaccin doit être dissous dans du liquide physiologique (habituellement 30 ml pour 1000 doses) et administré à l'aide d'un compte-gouttes standardisé. Une goutte doit être appliquée d'une hauteur de quelques centimètres dans une narine ou un oeil.
- Note:** Un diluant oculo-nasal Intervet est disponible dans le commerce dans plusieurs pays.

PROGRAMME DE VACCINATION

Le vaccin Nobilis Gumboro D78 peut être administré aux oiseaux dès l'âge de 8 à 28 jours. La souche D78 est efficace en présence d'anticorps maternels, existant habituellement dans les volées âgées de 8 à 28 jours. Le moment optimal de vaccination est fonction de l'importance du taux d'anticorps maternels. Au cas où le taux d'anticorps serait très variable à l'intérieur d'un même lot, il convient de vacciner les poulets deux fois à un intervalle d'une semaine.

Le vaccin Nobilis Gumboro D78 peut également être administré sans danger à un jour d'âge à des oiseaux ne présentant pas ou peu d'anticorps maternels.

Comme alternative, les oiseaux ne présentant pas d'anticorps maternels peuvent être vaccinés avec le vaccin Nobilis Gumboro PBG98 à l'âge d'un jour.

IMMUNITÉ

Les premiers signes de la réponse immunitaire ont été observés moins d'une semaine après la vaccination.

REACTION A LA VACCINATION

Des réactions post-vaccinales n'ont pas été observées après la vaccination de poulets sains.

DELAI D'ATTENTE:

aucun

PRECAUTIONS

- Laver et désinfecter les mains et les appareils après la vaccination. Tout vaccin excrétoire doit être détruit par incinération ou par ébullition.
- Chaque récipient doit être utilisé immédiatement et complètement après ouverture.
- Ne vacciner que des animaux sains.

CONDITIONS DE CONSERVATION

A conserver dans l'obscurité entre 2°C et 8°C.

PRESENTATIONS

Flacons de 500, 1000, 2000, 2500, 3000, 5000 ou 10 000 doses en paquet de 10 flacons.

Gobelets contenant 1000, 2500, 5000, 10 000 ou 25 000 doses en paquet de 1, 10 ou 50 gobelets

Product of/Producto de/Produit de:
INTERVET INTERNATIONAL B.V.

BOXMEER - HOLLAND

