SUMMARY OF PRODUCT FEATURES

1. Name of the veterinary medicinal product

NOBILIS GUMBORO 228 E

2. Qualitative and quantitative composition

One dose of reconstituted vaccine contains:

Active substance(s):

Live virus of avian infectious bursal disease,……..…… ≥ 2.0 $\log_{10}$ DIO_{50} - ≤ 3.0 $\log_{10}$ DIO_{50}

strain 228 E

For the full list of excipients, see section “List of excipients”.

3. Pharmaceutical form

Lyophilisate for administration in drinking water.

Vials: Light brown/reddish brown colored granules.

Cups: Light brown/reddish brown colored spheres.

4. Clinical information

4.1. Target species

Broiler chickens, future laying pullets, future breeding pullets from 10 days of age.

4.2. Indications for use, specifying the target species

In herds contaminated with a highly pathogenic strain of Gumboro disease: active immunization in the presence of an average maternal antibody level of 500 ELISA units to reduce mortality, clinical signs and lesions of the bursa of Fabricius.

Immunity is established within 14 days.
The duration of immunity is 4 weeks post-vaccination.

4.3. Contraindications

Do not vaccinate animals that do not carry maternally derived antibodies at birth.
Do not vaccinate during the laying period.

4.4. Specific warnings for each target species

Vaccine virus can spread to unvaccinated birds. The laboratory reversion to virulence test showed that the vaccine virus does not show any tendency to acquire any additional pathogenic character after six passages in chicken species. However, it is recommended to avoid spread, in particular, to laying animals.

4.5. Special precautions for use

i) Special precautions for use in animals

Vaccinate only healthy birds.
Follow the protocol for determining the day of vaccination.
Do not use equipment that may have contained a disinfectant.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash and disinfect your hands after vaccination.

iii) Other precautions

None.

4.6. Adverse reactions (frequency and severity)

In animals without antibodies and vaccinated by the ocular route at 7 days, a maximum lymphocyte depletion of the bursa of Fabricius is observed 7 days post-vaccination (80-100% lymphocyte depletion). The lymphocyte depletion regresses over time and at 28 days post-vaccination, it is on average 20 to 40% with values reaching 80-100% in a limited number of animals.

In animals with maternally derived antibodies and vaccinated by the ocular route at 7 days, a maximum lymphocyte depletion of the bursa of Fabricius is observed 3 days post-vaccination (with a maximum of 80 - 100% lymphocyte depletion for some animals). At 28 days, a notable repopulation of the bursa of Fabricius is observed, with lymphocyte depletion being only 0-20% on average, with values reaching 20-40% in a limited number of animals.

4.7. Use during pregnancy, lactation or laying

See “Contraindications” section.

4.8. Drug interactions and other forms of interaction

No information is available on the safety and effectiveness of using this vaccine with other vaccines. Due to potential immunosuppression, concomitant use of other vaccines is not recommended. It is recommended that no further vaccinations be given within 14 days of receiving this vaccine.

4.9. Dosage and route of administration

1 dose, i.e. 2.0-3.0 $\log_{10} DIO_{50}$ per animal, in drinking water from 10 days of age.

Since the presence of maternally derived antibodies is necessary but may interfere with vaccine uptake, the optimal age for vaccination should be determined so as to vaccinate on the day when the mean maternal antibody level in chicks is close to 500 ELISA units.

Mode of administration

The vaccine may be supplied as lyophilisate granules packaged in glass vials or as lyophilised spheres packaged in cups. For the latter presentation, the cups may contain 3 to 400 spheres depending on the required dosages and production yields. In the case of cup presentation, do not use the product if the contents stick to the container, indicating that the container has been punctured. Each container should be used immediately and completely after opening.

The vials should be opened under water or the contents of the cups should be poured into water. In both cases, mix the water containing the vaccine well before use. After reconstitution, the suspension has a clear appearance.

To reconstitute the vaccine, use water without disinfectant (chlorine in particular). Distribute the vaccine solution to birds previously deprived of water for 2 hours. Distribute a minimum quantity of vaccine water – expressed in liters per 1,000 birds – equal to the age of the chickens in days (e.g. 17-day-old chickens, minimum distribution of 17 liters per 1,000 chickens). Monitor distribution and consumption, in order to react to any problems. Distribution must last at least 1 hour 30 minutes.

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

No adverse reactions other than those mentioned in the section “Adverse reactions” were observed after administration of 10 doses of vaccine.

4.11. Waiting time

Zero days.

5. Immunological properties

ATC-vet code: QI01AD09.

The vaccine contains the live attenuated strain 228 E of the avian infectious bursal disease virus and induces active immunity against Gumboro disease. The strain used retains a high residual pathogenicity and allows to induce protection in the presence of a high level of maternal antibodies. Due to its high pathogenicity, this vaccine should be reserved for prophylaxis in environments contaminated by highly pathogenic strains of Gumboro disease.
The live attenuated strain 228 E of the avian infectious bursal disease virus causes a lesion score of 1.7 on the bursa of Fabricius 28 days after vaccination.

6. Pharmaceutical information

6.1. List of excipients

Freeze-drying substrate

Sucrose

Bovine serum albumin

Monopotassium phosphate

Disodium phosphate dihydrate

Sodium glutamate

Gentamicin sulfate

Water for injections

6.2. Major incompatibilities

Do not mix with other products.

6.3. Retention period

Shelf life of the veterinary medicinal product as packaged for sale: 2 years between 2°C-8°C.

Shelf life after reconstitution according to instructions: 2 hours at room temperature.

6.4. Special precautions for storage

Store between +2°C and +8°C, away from light.

6.5. Nature and composition of primary packaging

Type I hydrolytic glass vial
Halobutyl rubber stopper
Color-coded aluminum cap
Cup with polypropylene inner liner sealed with laminated aluminum foil
Polypropylene/polyethylene lid

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

Before disposal, disinfect empty vials or vials containing unused vaccine residue.
Empty vials and any remaining product must be disposed of in accordance with current practices governed by waste regulations.

7. Marketing authorisation holder

INTERVET
RUE OLIVIER DE SERRES
ANGERS TECHNOPOLE
49071 BEAUCOUZE CEDEX
FRANCE

8. Marketing authorisation number(s)

FR/V/6064945 0/2002

Box of 1 vial of 1,000 doses
Box of 10 vials of 1,000 doses
Box of 1 vial of 2,000 doses Box of
10 vials of 2,000 doses
Box of 1 vial of 2,500 doses Box of 10
vials of 2,500 doses
Box of 1 vial of 3,000 doses
Box of 10 vials of 3,000 doses Box
of 1 vial of 5,000 doses
Box of 10 vials of 5,000 doses
Box of 1 vial of 10,000 doses Box of
10 vials of 10,000 doses
Box of 12 cups of 1,000 doses
Box of 12 cups of 2,500 doses
Box of 12 cups of 5,000 doses
Box of 12 10,000 dose cups
Box of 6 10,000 dose cups

Not all presentations may be marketed.

9. Date of first authorization/renewal of authorization

27/11/2002 - 09/07/2012

10. Date of text update

05/07/2021