

ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN GUMBORO W2512 Lyophilisate for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:

Live attenuated avian infectious bursal disease (IBD) virus, intermediate plus IBDV_2512 strain, 1.5 - 3.0 log₁₀ EID₅₀*

* EID₅₀ (embryo infectious dose 50%)

Excipients:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water

Appearance: Freeze-dried pellet with white-beige colour

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (broiler)

4.2 Indications for use, specifying the target species

For the active immunisation of broiler chickens with maternally derived antibodies (MDA) to reduce mortality, clinical disease and acute lesions in the bursa of Fabricius associated with infection caused by very virulent strains of infectious bursal disease viruses.

Onset of immunity: 14 days post vaccination.

Duration of immunity: 28 days.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

As described in section 4.5, the vaccine contains an "intermediate-plus" virus strain that is known to cause immunosuppression and bursal damage. Consequently, the vaccine is only

indicated for immunisation of chickens with MDAs and exposed to very virulent IBD virus strains. The ideal day for vaccination is calculated according to the Deventer's formula (see section 4.9), using 450 as the ELISA breakthrough titre value (which is the MDA titre that has no negative impact on the protection induced by the vaccine).

4.5 Special precautions for use

Special precautions for use in animals

Birds younger than 7 days of age should not be vaccinated. The vaccine contains an "intermediate-plus" virus strain, causing significant immunosuppression and bursal damage when inoculated into birds without MDA.

The product should be only used after it has been demonstrated that very virulent IBDV strains are epidemiologically relevant in the area in which the farm is located.

Vaccinated birds may excrete the vaccine virus for at least 21 days. Appropriate veterinary and husbandry measures should be taken to avoid spreading of the vaccine strain to other birds. Especially, spread should be prevented to chickens without MDAs, laying hens, birds approaching lay and young birds below 7 days of age.

Vaccinate all susceptible birds on the premises at the same time.

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

- Personal protective equipment consisting of gloves and boots should be worn when handling the veterinary medicinal product.
- The vaccine strain can be detected in the environment for at least 21 days. Personnel involved in attending vaccinated chicks should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated chicks to prevent spreading of the vaccine strain.
- Wash and disinfect hands and equipment after vaccinating.

4.6 Adverse reactions (frequency and seriousness)

A notable transient lymphocyte depletion can be very commonly observed in birds on day 7 post-vaccination. The repopulation of the bursa of Fabricius follicles by lymphocytes starts after day 7 post-vaccination. By day 28 post-vaccination only mild lesions remain in some birds. These lesions do not result in an immuno-suppressive effect.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Laying birds

The safety of the veterinary medicinal product has not been established during lay.

Do not use in birds in lay and within 4 weeks before the onset of the lay.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

Dosage: One dose per animal should be administered by drinking water from the age of 7 days onwards.

Vaccination programme:

The determination of the vaccination date depends on a number of factors including status of maternal derived antibodies (MDAs), type of bird, infection pressure, housing and management conditions.

In the case of a vv(very virulent)-IBD field challenge, the field virus is extraordinarily virulent and requires the use of a vaccine able to break through relatively high levels of MDAs. The vaccine can break through an ELISA-antibody level of 450 ELISA units.

Homogenous levels of MDAs facilitate a more accurate timing of the vaccination.

To predict the age, when MDA have sufficiently decreased to allow effective vaccination, samples of at least 18-20 chicks should be tested serologically and the "Deventer Formula" should be used to calculate the optimum age of vaccination.

Optimum age of vaccination =
 $\{(\log_2 \text{ IBV antibodies ELISA titre of bird } \% - \log_2 \text{ breakthrough titre of the vaccine}) \times t_{\frac{1}{2}}\} + \text{age at sampling} + \text{correction } 0-4$

bird % = ELISA titre of the bird representing a certain percentage of the flock.

$t_{\frac{1}{2}}$ = half-life time (ELISA) of the antibodies in the type of chickens being sampled

Age at sampling = age of the birds at sampling

Correction 0-4 = extra days when the sampling was done at 0 to 4 days of age)

According to this formula the optimum age of vaccination is calculated as follows:

1. Decide what percentage of the flock shall be representing and remove the highest titres that are excluded (e.g. 75 % of the flock; remove the highest 25 % of the titres).
2. Calculate the mean ELISA antibody titre of these birds.
3. Calculation of the optimal age of vaccination age.

Birds should be at least 7 days of age at vaccination. The optimum age for vaccination may be calculated using the level of MDAs of the chicks at one-day-old (Deventer formula), but usually ranges between 12-21 days.

Administration route: in drinking water use

Preparation and administration of the vaccine:

Remove the aluminium seal from the vaccine vial. To dissolve the vaccine pellet, the rubber stopper should be removed only whilst the vial is immersed in a plastic measuring jug containing the required volume of clean cool water. Fill the vial half with water, replace the stopper and shake to dissolve any remaining vaccine. The vaccine concentrate should then be added to the drinking system.

Important points to be considered for a successful vaccination:

1. The required number of vaccine doses should be added to the correct amount of drinking water calculated upon previous water consumption of the birds to be immunized.
2. Do not split large vials to vaccinate more than one poultry house or drinking system, as this may lead to dosing errors
3. Make sure that all conduit pipes, tubing, troughs, drinkers etc are thoroughly clean and free of any traces of disinfectants, detergents etc. Use only cold, fresh non-chlorinated water free from disinfectants, detergents and metal-ions to ensure the viability of the vaccine.
4. Drinking water should be withdrawn from birds for 2-4 hours prior to vaccination, depending on their age and the temperature of the house.
5. To preserve virus activity, it is advised to dissolve 2-4 g skimmed milk powder per litre of calculated drinking water or skimmed milk (20 - 40 ml/litre of water), prior to dissolving the vaccine.
6. It is recommended to increase the number of drinkers during vaccination. To ensure that all birds have access to the vaccinated water, it is advised to move birds around the drinkers in the first few minutes of vaccination. The birds can be supplied with fresh drinking water only after the medicated water was consumed entirely.
7. The vaccine should be administered to birds immediately after reconstitution.
8. Vaccine administration has to be finalised within 2 hours after reconstitution
9. Protect the reconstituted vaccine from direct sunshine.

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

From studies involving a 10 fold overdose of PRIMUN GUMBORO W2512 administered to 7-day-old broiler chickens without MDAs (SPF chickens) no adverse reactions different from those mentioned under 4.6. were detected.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live viral vaccines for domestic fowl, avian infectious bursal disease virus (Gumboro disease).

ATCvet code: QI01AD09

For active immunisation against infection with very virulent strains of infectious bursal disease virus (Gumboro disease, IBDV).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate anhydrous

Potassium dihydrogen phosphate

Lactose monohydrate

Skimmed milk powder

Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medical product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after reconstitution according to directions: 2 hours

6.4. Special precautions for storage

Store and transport refrigerated (2°C – 8°C). Do not freeze.

Protect from light.

6.5 Nature and composition of immediate packaging

Lyophilised vaccine: 1000 doses in type I glass vials of 10 ml, sealed with bromobutyl rubber stopper and aluminium cap with red lid.

Cardboard box with 1 vial of 1000 doses

Plastic box with 10 vials of 1000 doses

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

[To be completed in accordance with national requirements]

9. DATE OF FIRST AUTHORISATION

[To be completed in accordance with national requirements]

10. DATE OF REVISION OF THE TEXT

[To be completed in accordance with national requirements]