ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMUN GUMBORO, Lyophilisate for use in drinking water for chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:

Avian infectious bursal disease (IBD) virus, live attenuated, intermediate IBDV_IGS strain, 3.0 - 4.5 log10 EID_{50}*

* EID_{50} (embryo infectious dose 50%)

Excipients:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water.

Freeze-dried pellet with white-beige to white-brown colour

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

For the active immunisation of chickens with maternally derived antibodies (MDA) against Infectious Bursal Disease (Gumboro disease) to reduce mortality, clinical disease and acute lesions in the bursa of Fabricius.

Onset of immunity: 2 weeks.

Duration of immunity: 28 days.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The optimal day of vaccination is calculated according to the Deventer's formula (see section 4.9), using 150 as the ELISA breakthrough titre value (which is the MDA titre that has no negative impact on the protection of the vaccine).

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinated chickens may excrete the vaccine strain up to 7 days following vaccination. During this time the contact of immunosuppressed and unvaccinated chickens with vaccinated chickens should be avoided.

It is recommended to vaccinate all birds on a site at the same time.

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

- - Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.
- - Wash and disinfect hands and equipment after use.
- - In case of accidental ingestion, contact with the eyes, or spillage onto the skin seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A significant transient decrease in lymphocytes can commonly be observed in SPF birds, 7 days post-vaccination. The lymphocyte repopulation begins at 7 days post-vaccination, being especially evident at 21 days after vaccination. At 28 days after vaccination, only slight lesions remain in some birds. In SPF birds no immunosuppression could be shown in safety studied.

In case of MDA birds, more severe bursa lesions have been observed up to 28 days after vaccination. These bursa lesions decrease in 10 days and the repopulation of lymphoid follicles is evident in all animals associated to a progressive increase of the cortical and medullary lymphocyte density. A potential immunosuppressive effect in MDA-positive birds has not been investigated.

<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 start of the laying period.

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

Most of the commercial chicks are hatched with maternal antibodies which might neutralize the vaccine. Due to this fact it is required to calculate the proper vaccination time.

The optimum age for vaccination is calculated, after testing the level of maternal antibodies of 18-20 chicks of the flock, by means of the Deventer Formula.

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

Optimum vaccination age =

{(Log_2 IBD antibody ELISA titre of bird(%) - Log_2 breakthrough titre of the vaccine) x $t_{0.5}$}

+ age at sampling + correction 0-4

IBD antibody ELISA titre of bird(%):

ELISA titre of the bird (at sampling) representing a certain percentage of the flock that is desired to be susceptible to the vaccine at the time of the application

Breakthrough titre of the vaccine:

ELISA titre that the vaccine is able to breakthrough

$t_{0.5}$:

Half-life time of the antibodies (ELISA titre) 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.

The optimal day of vaccination is calculated according to the Deventer's formula, using 150 as the ELISA breakthrough titre value (which is the MDA titre that has no negative impact on the protection of the vaccine).

Vaccination scheme:

The optimal timing of vaccination should be determined on the basis of ELISA titers measured in 1- to 4 day-old chickens.

Chickens should be vaccinated with the product from 7 to 28 days of age, depending on the level of maternally derived antibodies.

Administration route: in drinking water use.

Remove the aluminium seal from the vaccine vial. To dissolve the vaccine pellet, the rubber stopper should be removed whilst the vial is immersed in a plastic measuring jug containing the

required volume of clean cool water. Half fill the vial with water, replace the stopper and shake to dissolve any remaining vaccine. The vaccine concentrate should then be added to the drinking system.

Oral administration via reconstitution in drinking water:

Preparation and administration of the vaccine:

- The number of vaccine doses should be dissolved in the amount of drinking water calculated upon previous water consumption of the birds to be immunized.
- Number of doses should be rounded up for smaller flocks and dissolved accordingly. Do not split large vials to vaccinate more than 1 house or drinking system, as this may lead to mixing errors
- Ensure that the drinking water and all equipment used for vaccination (tubes, drinkers, etc) are carefully cleaned and do not contain any residues of detergents, disinfectants or metal ions.
- Drinking water should be withdrawn from birds for 2 to 4 hours prior to vaccination, depending on their age and the temperature of the house.
- 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.
- It is advised 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 is consumed entirely.

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

No adverse reactions other than those indicated in section 4.6 have been observed following administration of ten doses.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: avian infectious bursal disease virus (Gumboro disease).

ATC vet code: QI01AD09

For active immunisation against infection with infectious bursal disease virus (Gumboro disease, IBD).

The vaccine contains live, attenuated, intermediate IBDV_IGS strain of IBD virus. The vaccine strain IGS is an intermediate strain.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Disodium phosphate

- 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 ($2^{o}C$ – $8^{o}C$).

Protect from light.

6.5 Nature and composition of immediate packaging

Lyophilised vaccine: 1,000 doses in type I glass vials of 10 ml, sealed with bromobutyl rubber stoppers and aluminium cap with green lid.

Cardboard box with 1 vial of 1,000 doses

Plastic box with 10 vials of 1,000 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

xxxx

9. DATE OF FIRST AUTHORISATION

xxxx

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, posses, sell, supply and use Primun Gumboro must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.