1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursa Plus Lyophilisate for suspension in drinking water

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	Per dose
Live Infectious Bursal Disease Virus, strain V877	$10^{2.2}$- $10^{3.4}$ EID_{50}*

*50% egg infective dose

Excipients

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Lyophilisate for suspension in drinking water.
Appearance: brownish tablets.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens, from 10 days of age.

4.2 Indications for use, specifying the target species

For the active immunisation of chickens with maternal antibody levels of ≤ 500 ELISA units, to reduce mortality and bursal lesions of Gumboro disease.
The onset of immunity has been shown by challenge from 14 days after vaccination and the duration of immunity is 32 days.

4.3 Contraindications

Do not vaccinate sick birds.
Do not use in infected flocks showing clinical signs.

4.4 Special warnings for each target species

Use only in flocks with maternal antibody levels of ≤ 500 ELISA units. The optimum day of vaccination is calculated according to the Kouwenhoven's formula (see section 4.5. Special precautions for use).
Due to its residual pathogenicity to the bursae the vaccine should be used only in case of outbreaks of very virulent IBDV strains.

4.5 Special precautions for use

i)Special precautions for use in animals

Use carefully as Poulvac Bursa Plus spreads from bird to bird and may also spread to nearby flocks. Reversion to virulence studies conducted at the laboratory level demonstrated that there is no increase in virulence after 5 passages in chickens. However, it is recommended to avoid spreading, especially to laying birds.

The optimum age for vaccination may be determined with the following method:
Determine the ELISA* antibody titres against Gumboro Disease in 20 chickens of 1 day of age.
For each result, calculate the square root.
Calculate the average square root for all data (M).
The age for vaccination (J) is calculated with the formula:

$$J = 1 + \frac{(M - 22.36)}{2.82}$$

*Method valid for data collected with the Idexx FlockChek®: Anti-IBD assay kit.

Whatever the vaccination day calculation reaches, do not vaccinate birds less than 10 days of age.

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

Wash and disinfect hands and equipment after vaccination.

iii)Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

The administration of a single dose to 10-day old chickens causes lymphocyte depletion in the bursa of Fabricius (in 75-100% of the follicles). Lymphocyte repopulation is observed from 21 days post vaccination onwards. At 28 days post vaccination there is still depletion remaining (25-75 % of follicles). As a consequence vaccination with Poulvac Bursa Plus may induce immunosuppression.

4.7 Use during pregnancy, lactation or lay

Do not use in laying or breeding hens.

4.8 Interaction with other medicinal products and other forms of interaction

Interaction with vaccination against Newcastle Disease has been studied. No significant interference in protection against Newcastle Disease virus virulent challenge is observed in birds vaccinated at 10 days of age with Poulvac Bursa Plus and 7 days later with a live Newcastle disease vaccine. However, a statistically lower serological response to Newcastle Disease virus was observed in birds vaccinated with Poulvac Bursa Plus. As a consequence a transient immunodepression following vaccination with Poulvac Bursa Plus cannot be excluded.
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

One dose per chicken to be administered with drinking water from 10 days of age.
Make sure that all conduit pipes, tubing, troughs, drinkers etc are thoroughly clean and free of any trace of disinfectants, detergents, soap, etc.
Allow water to be consumed so that levels in drinkers are minimal before vaccine is applied. If water is still present, drain lines before applying vaccine. Apply vaccine over up to 3 hours, ensuring that all birds drink during this time. Birds' drinking behaviour varies. It may be necessary to withhold water on some sites prior to vaccination in order to ensure that all birds drink during the vaccination period. The aim is to give every bird one dose of vaccine.
Water used for drinking water administration of a live virus vaccine must be non-chlorinated and contain as few as possible metal ions. This can be achieved by allowing mains water to stand for 12 hours or by use of deionised water. The addition of milk powder (low-fat skimmed milk powder, <1% fat, 2-4 grams per litre) or skimmed milk (1 litre per 40 litres of water) is recommended where this is not possible to increase the stability of the virus.
Open the vaccine ampoule under water and dissolve thoroughly. As the concentrated vaccine is slightly viscous, care should be taken to empty the ampoule and its top completely by rinsing them in water. Then, thoroughly dissolve in a 1 litre container and stir well before mixing with more water in a 10-litre container before application. Vaccine must be stirred thoroughly for several minutes at each stage. Do not split large vials to vaccinate more than 1 house or drinking system, as this leads to mixing errors. Apply diluted vaccine to cold and fresh water at the rate of 1,000 doses of the vaccine to 1 litre of water per day of age for 1,000 chickens, e.g. 10 litres would be needed for 1,000 10-day old chickens.

All tubing should be emptied of plain water, so that the drinkers contain only vaccine water. Ideally vaccine should be administered in the volume of water consumed by the birds in up to 3 hours. If in doubt, measure water intake the day before administering vaccine.
Administer the dissolved vaccine to birds immediately after dilution.
Avoid exposure of the vaccine suspension to sunlight.
Avoid stress in the birds around vaccination.

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

After administration of a 10x overdose, no other adverse reactions than those reported at section 4.6 “Adverse reactions” are observed.

4.11 Withdrawal period(s)

Zero Days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Infectious Bursal Disease (Gumboro disease) Virus.
The vaccine strain V877 is classified as an Intermediate Plus IBDV vaccine strain.
Vaccine strain V877 induces a lesion score of around 2.7 to the bursa of Fabricius observed 28 days after administration of 50 maximum doses to 10-day old chickens.
ATC Vet code: QI01AD09

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium dihydrogen phosphate
Dipotassium phosphate
Bovine serum albumin fraction V

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as package for sale: 21 months.
Shelf-life after reconstitution according to directions: use within 4 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2°C - 8°C).
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Bottle: Type I (Ph. Eur.) glass bottles.
Closure: Type I (Ph. Eur.) butyl rubber stoppers sealed withaluminium overseal.
Pack Sizes: 1x1000, 1x2000, 1x5000, 10x1000, 10x2000 or 10x5000 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

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

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/049/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th March 2010
Date of last renewal: 29thAugust 2013

10 DATE OF REVISION OF THE TEXT

October 2017