

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursa Plus lyophilisate for suspension for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substances:

Infectious bursal disease virus, strain V877, Live $10^{2.2} - 10^{3.4}$ EID₅₀*

* EID₅₀ = 50% embryo infective dose.

Excipients:

Qualitative composition of excipients and other constituents
Sodium dihydrogen phosphate
Dipotassium phosphate
Bovine serum albumin

Beige to mid-brown lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (from 10 days of age).

3.2 Indications for use for each target species

For the active immunisation of chickens with maternal antibody levels of ≤ 500 ELISA units, to reduce mortality and bursal lesions of infectious bursal disease (Gumboro disease).

Onset of immunity: 14 days after vaccination.

Duration of immunity: 32 days after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Use only in flocks with maternal antibody levels of ≤ 500 ELISA units.

Vaccinate healthy animals only.

Due to its residual pathogenicity to the bursae, the vaccine should be used only in case of outbreaks of very virulent IBDV strains.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use carefully as the veterinary medicinal product 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.

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

Personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots).

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Bursa of Fabricius lymphocyte depletion ¹
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¹ Notable in 75-100 % of the follicles.

Lymphocyte repopulation begins from 21 days post vaccination. At 28 days post vaccination in 25-75 % of follicles are still depleted. As a consequence, vaccination with Poulvac Bursa Plus may induce immunosuppression.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:

Do not use in laying or breeding hens.

3.8 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 challenge with virulent Newcastle disease virus is observed in birds vaccinated at 10 days of age with the veterinary medicinal product and 7 days later with a live Newcastle disease

vaccine. However, a statistically significant lower serological response to Newcastle disease virus was observed in birds vaccinated with the veterinary medicinal product. As a consequence, a transient immunodepression following vaccination with the veterinary medicinal product 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.

3.9 Administration routes and dosage

One dose per chicken from 10 days of age to be administered with drinking water.

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 the vaccine.

Administer the dissolved vaccine to birds immediately after dilution.

Upon reconstitution, white to pink-orangish opaque suspension (depending on the volume of water used).

Avoid exposure of the vaccine suspension to sunlight.

Avoid stress in the birds around vaccination.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

After administration of a 10-fold overdose, no other adverse reactions than those reported under section 3.6 "Adverse events" are observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD09

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

5.4 Nature and composition of immediate packaging

Type I (Ph. Eur.) glass bottles closed with a Type I (Ph. Eur.) butyl rubber stopper and sealed with an aluminium overseal.

Pack sizes:

Cardboard box of 1 x 1 000 doses.

Cardboard box of 1 x 2 000 doses.

Cardboard box of 1 x 5 000 doses.

Cardboard box of 10 x 1 000 doses.

Cardboard box of 10 x 2 000 doses.

Cardboard box of 10 x 5 000 doses.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/049/001

8. DATE OF FIRST AUTHORISATION

09/12/2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

19/11/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).