PARTICULARS TO APPEAR ON THE OUTER PACKAGE BOX OF 1 OR 10 VIALS, EACH CONTAINING 1,000, 2,000 OR 5,000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursa Plus lyophilisate for suspension for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Infectious bursal disease virus, strain V877, Live $10^{2.2}$ - $10^{3.4}$ EID_{50}/dose*
* EID_{50} = 50% embryo infective dose.

3. PACKAGE SIZE

1 x 1,000 doses
1 x 2,000 doses
1 x 5,000 doses
10 x 1,000 doses
10 x 2,000 doses
10 x 5,000 doses

4. TARGET SPECIES

Chickens (from 10 days of age).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5138

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS GLASS VIAL WITH 1,000, 2,000 OR 5,000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursa Plus

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

IBDV, strain V877, Live $10^{2.2}$ - $10^{3.4}$ EID_{50}/dose

1,000 doses
2,000 doses
5,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 4 hours.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each dose contains:

Active substances:

Infectious bursal disease virus, strain V877, Live $10^{2.2}$ - $10^{3.4}$ EID_{50}* per dose
* $EID_{50=}$ 50% embryo infective dose

Beige to mid-brown lyophilisate.

3. Target species

Chickens (from 10 days of age).

4. Indications for use

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

Onset of immunity: 14 days after vaccination.
Duration of immunity: 32 days after vaccination.

5. Contraindications

None.

6. Special warnings

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.

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).

Laying birds:
Do not use in laying or breeding hens.

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 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.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product 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

Overdose:
Administration of a 10-fold overdose does not result in symptoms different from those mentioned under the section “Adverse events”.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:

Very common (>1 animal / 10 animals treated):	Bursa of Fabricius lymphocyte depletion[1]

[1] Notable in 75-100 % of the follicles.
Lymphocyte repopulation begins from 21 days post vaccination. At 28 days post vaccination 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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

9. Advice on correct administration

Avoid exposure of the vaccine suspension to sunlight.
Avoid stress in the birds around vaccination.

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.

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

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the reach and sight of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the vial after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: use within 4 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5138

The vaccine is supplied in quantities of 1,000, 2,000 or 5,000 doses per vial in a cardboard box of 1 or 10 vials.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
+44 (0) 345 300 8034

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

17. Other information

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.

POM-V

Gavin Hall

Approved: 24 February 2026