

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 x 1000 doses, 10 x 1000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursa Plus, lyophilisate for suspension in drinking water.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live Infectious Bursal Disease Virus, strain V877 102.2 - 103.4 EID₅₀* per dose
* 50% egg infective dose

3. PHARMACEUTICAL FORM

Lyophilisate for suspension in drinking water

4. PACKAGE SIZE

1 x 1,000 doses
10 x 1,000 doses

5. TARGET SPECIES

Chickens from 10 days of age.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration in drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Reconstituted vaccine should be used within 4 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - To be supplied only on veterinary prescription

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4098

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 x 2000 doses or 10 x 2000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursa Plus, lyophilisate for suspension in drinking water.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live Infectious Bursal Disease Virus, strain V877 102.2 - 10^{3.4} EID₅₀* per dose
* 50% egg infective dose

3. PHARMACEUTICAL FORM

Lyophilisate for suspension in drinking water

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens from 10 days of age.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration in drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Reconstituted vaccine should be used within 4 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - To be supplied only on veterinary prescription

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4098

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 x 5000 doses or 10 x 5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursa Plus, lyophilisate for suspension in drinking water.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live Infectious Bursal Disease Virus, strain V877 102.2 - 103.4 EID₅₀* per dose
* 50% egg infective dose

3. PHARMACEUTICAL FORM

Lyophilisate for suspension in drinking water

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens from 10 days of age.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration in drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Reconstituted vaccine should be used within 4 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - To be supplied only on veterinary prescription

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4098

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1,000 doses, 2,000 and 5,000 glass vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursa Plus

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live IBDV, strain V877 102.2 - 103.4 EID50 per dose

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

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

4. ROUTE(S) OF ADMINISTRATION

For administration in drinking water.

5. WITHDRAWAL PERIOD

Withdrawal period: zero days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Reconstituted vaccine should be used within 4 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
POULVAC BURSA PLUS, lyophilisate for suspension in drinking water.

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for the batch release:

Zoetis Manufacturing & Research Spain, S.L
C/Camprodon s/n "La Riba"
17813 Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursa Plus
Lyophilisate for suspension in drinking water.

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER
INGREDIENT(S)**

Live Infectious Bursal Disease Virus, strain V877 : 102.2 - 103.4 EID₅₀* per dose
* 50% egg infective dose
Appearance : brownish tablets

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens, from 10 days of age.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL PRECAUTIONS FOR STORAGE

Store and transport refrigerated (2°C – 8°C).
Protect from light.
Do not freeze.
Shelf-life after reconstitution according to directions : use within 4 hours.
Do not use after the expiry date stated on the label.
Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

Special precautions for use in animals

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

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.

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.

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

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.

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 significantly lower serological response to Newcastle Disease virus was observed in birds vaccinated with Poulvac Bursa Plus.

Do not mix with any other veterinary medicinal product. 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.

Do not use in laying or breeding hens.

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

Wash and disinfect hands and equipment after vaccination.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2013

15. OTHER INFORMATION

For Animal Treatment Only.

To be supplied only under veterinary prescription.

The vaccine strain V877 is classified as an Intermediate Plus IBDV vaccine strain.

A Member State may, in accordance with its national legislation, prohibit the import, possession, sale, supply and/or use of Poulvac Bursa [Plus] on the whole or part of its territory if it is established that the disease to which the product is intended to confer immunity is largely absent from the territory in question.

ATC VET CODE: QI01AD09

LEGAL CATEGORY

To be supplied only on veterinary prescription.

PACKAGE QUANTITIES

1 x 1000 doses
1 x 2000 doses
1 x 5000 doses
10 x 1000 doses
10 x 2000 doses
10 x 5000 doses

Not all pack sizes may be marketed.

To be supplied only under veterinary prescription.

MARKETING AUTHORISATION NUMBER

Vm 42058/4098

Approved 14 November 2019

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date.