PARTICULARS TO APPEAR ON THE OUTER PACKAGE BOX OF 10 X 1,000 DOSES, 10 X 2,000 DOSES, 10 X 2,500 DOSES, 10 X 5,000 DOSES, 10 X 10,000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursine 2 lyophilisate for suspension for spray vaccination or for use in drinking water.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Infectious bursal disease virus, strain Lukert, Live ≥ $10^{4.3}$ $TCID_{50}$/dose

3. PACKAGE SIZE

10 x 1,000 doses
10 x 2,000 doses
10 x 2,500 doses
10 x 5,000 doses
10 x 10,000 doses

4. TARGET SPECIES

Chickens (broilers and future layers/breeders).

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Spray vaccination or for use in drinking water.

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.
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 42058/5137

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read the package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS VIALS OF 1,000 DOSES, 2,000 DOSES, 2,500 DOSES, 5,000 DOSES, 10,000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursine 2

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Infectious Bursal Disease virus, strain Lukert, Live ≥$10^{4.3}$ $TCID_{50}$/dose

1,000 doses
2,000 doses
2,500 doses
5,000 doses
10,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

Coarse spray or in drinking water use.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursine 2 lyophilisate for suspension for spray vaccination or for use in drinking water for chickens

2. COMPOSITION

Each dose contains:

Active substances:

Infectious bursal disease virus, strain Lukert ≥ $10^{4.3}$ $TCID_{50}$*

*$TCID_{50}$ = 50% tissue culture infective dose.

Beige to mid-brown, lyophilised.

3. TARGET SPECIES

Chickens (broilers and future layers/breeders).

4. INDICATIONS FOR USE

For the active immunisation of broilers, and future layers/breeders to reduce clinical signs caused by infectious bursal disease virus.

Onset of immunity: 2 days after vaccination.

Duration of immunity: 7 weeks after spray vaccination and
4 weeks after vaccination via drinking water.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:
Vaccinate healthy animals only.
Maternally derived antibodies (MDA) can interfere with the development of active immunity. Where it is likely that recent field infection or vaccination of the parent flock has stimulated a high antibody titre and consequently a high level of MDA, the timing of the vaccination programme should be planned accordingly.

Very virulent infectious bursal disease virus can breakthrough higher maternal antibody levels than vaccine virus.

Field infection is capable therefore of reaching birds before vaccine has a chance to take. Only use as part of a complete infectious bursal disease control programme

involving hygiene, biosecurity, management, stocking density and disinfection, etc. Overwhelming levels of field virus may overcome vaccinal immunity.

Special precautions for safe use in the target species:
The vaccine virus can spread to in contact birds.

Care should be taken to ensure that the vaccine virus does not spread to unvaccinated birds. It is recommended to vaccinate all chickens on a site at the same time. Cleaning and disinfection of the premises is advisable between flocks.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
If spray vaccination is applied, the user must at least protect their eyes with safety goggles and nose and mouth with a dust mask. A helmet with filtered air circulation may be used instead. It is recommended to wash and disinfect hands and equipment after vaccinating.

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Zoetis's live avian infectious bronchitis virus, strain H120 in 1 day old broilers.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

Overdose:
No reactions other than those reported following a single dose are expected after an overdose.

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

7. ADVERSE EVENTS

Chickens (broilers and future layers/breeders):

Very common (>1 animal / 10 animals treated):
Bursal of Fabricius degeneration[1], Other immune system disorder[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Application site reaction[2], Avian systemic disorder[2]

[1]The veterinary medicinal product produces increasing bursal damage on bird to bird passage and this is accompanied by a degree of immunosuppression (reduction in the activation or efficacy of the immune system).

[2]Reactions are usually transient.

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:

United Kingdom (Northern Ireland)

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

Coarse spray or in drinking water use.

Vaccination schedule:
Future layers/breeders:
Administer via drinking water.
One dose to chickens at 7 to 28 days of age. A second vaccination should be administered at 7 to 10 days after the first vaccination.

Broilers:
Administer via spray or drinking water.
One dose to chickens from 1 day of age.
Depending on the level of field virus present, repeat administration of the vaccine may be required at 7 to 10 days after the first vaccination. If not vaccinated at day old, it is recommended to determine the date of first vaccination according to the level of maternally derived antibodies (MDAs).
Nipple-drinking systems are not an appropriate method of vaccine delivery for 1-3 day old chicks.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitution of vaccine:
Upon reconstitution, light peach to a tan-brownish suspension depending on volume of water added.

Fill a container with an appropriate amount of preferably cold, fresh, non-chlorinated water that is free from metal-ions. Chlorine at levels as low as 1 ppm is known to have a detrimental effect on vaccine virus stability, therefore it's recommended for drinking water application to add low-fat skimmed milk powder (i.e. < 1% fat, 2–4 grams per litre) or skimmed milk (20–40 ml per litre of water) to the water to prolong the life of the virus in the vaccine suspension. Only skimmed milk should be used, as the fat in whole milk may block the automatic drinking systems as well as reduce vaccine virus efficacy. After mixing, the solution should be allowed to stand for 15–30 minutes before adding the vaccine.

Remove the cap of the vaccine vial. Open the vaccine vial under water and dissolve thoroughly in the container. Empty the vaccine vial completely by rinsing the vial and the stopper in the water.
Administer to birds immediately after dilution.
Avoid exposure of the vaccine suspension to sunlight.

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. Contact with disinfectants makes the vaccine ineffective.
Allow water to be consumed so that levels in drinkers are minimal before vaccine is applied. All tubing should be emptied of plain water, so that the drinkers contain only vaccine water. It may be necessary to withhold water prior to vaccination in order to ensure that all birds drink during the vaccination period. Ideally, vaccine should be administered in the volume of water consumed by the birds in up to 3 hours. The aim is to give every bird one dose of vaccine. As a general rule, apply reconstituted vaccine to chlorine-free 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. If in doubt, measure water intake the day before administering vaccine.

Coarse Spray:
This method is for day old broiler chicks only and may be used in the hatchery or on farm.
Use clean vaccination materials only. No disinfectants or other substances impairing the performance of the live vaccine should be used in the sprayer.
Dilute and administer the reconstituted vaccine at a rate of one dose of reconstituted vaccine per bird, according to the directions of your specific coarse spray vaccination equipment. The recommended volume for 1 dose is between 0.1 and 0.5 ml. The spraying distance should be between 30 and 80 cm above the animals in order to ensure an even distribution and the recommended droplet size is greater than 100 µm.
Turn off ventilation during vaccination.
Ensure that birds are neither overheated nor chilled following coarse spray.

10. WITHDRAWAL PERIODS

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5137

The vaccine is supplied in boxes of 10 vials of 1,000, 2,000, 2,500, 5,000 or 10,000 doses.

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 reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
United Kingdom
+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 virus (Gumboro Disease).
The vaccine contains the live intermediate IBDV strain Lukert.

POM-V
Veterinary medicinal product subject to prescription

For animal treatment only.

Gavin Hall

Approved: 09 June 2026