

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 10 x 1000 doses, 10 x 2000 doses, 10 x 2500 doses, 10 x 5000 doses, 10 x 10000 doses

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. STATEMENT OF ACTIVE SUBSTANCES

Infectious Bursal Disease virus, strain Lukert $\geq 10^{4.3}$ TCID₅₀ / dose

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for spray vaccination or for use in drinking water

4. PACKAGE SIZE

10 x 1000 doses
10 x 2000 doses
10 x 2500 doses
10 x 5000 doses
10 x 10000 doses

5. TARGET SPECIES

Chickens (broilers and future layers/breeders).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Once reconstituted use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

Protect from light.

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

Disposal: read the 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 SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach 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(S)

Vm 42058/4099

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 1000 doses, 2000 doses, 2500 doses, 5000 doses, 10000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursine 2

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Infectious Bursal Disease virus $\geq 10^{4.3}$ TCID₅₀/ dose

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

1000 doses
2000 doses
2500 doses
5000 doses
10000 doses

4. ROUTE(S) OF ADMINISTRATION

Coarse spray or in drinking water use.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

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 batch release:

Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona, Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

One dose contains:

Active substance

Live attenuated infectious bursal disease, strain Lukert $\geq 10^{4.3}$ TCID₅₀*

*TCID₅₀ = 50% tissue culture infective dose

Beige to mid-brown, lyophilized.

4. INDICATION(S)

For the active immunization of broilers and future layers/breeders to reduce clinical signs caused by Infectious Bursal Disease virus.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Local and/or general reactions after administration of the vaccine can be observed very rarely. Reactions are usually transient.

Poulvac Bursine 2 produces increasing bursal damage on bird to bird passage and this is accompanied by a degree of immunosuppression.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (broilers and future layers/breeders).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Use clean vaccination materials.

Avoid exposing the reconstituted vaccine to heat and/or direct sunlight.

Contact with disinfectants makes the vaccine ineffective.

10. WITHDRAWAL PERIOD

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.

Shelf-life after reconstitution according to directions: 4 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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 use in animals:

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.

Lay:

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:

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product, except for the concurrent use with Poulvac IB H120 administered to broilers at 1 day of age. A decision to use this vaccine before or after any other veterinary medicinal product, besides Poulvac IB H120, therefore needs to be made on a case by case basis.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

Overdose (symptoms, emergency procedures, antidotes):

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

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2022

15. OTHER INFORMATION

The vaccine is supplied in boxes of 10 vials of 1000, 2000, 2500, 5000 or 10000 doses.

Not all pack sizes may be marketed.

Approved 28 July 2022

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