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. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substances:

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

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

Excipients:

Qualitative composition of excipients and other constituents
Sucrose
Sodium dihydrogen phosphate dihydrate
Dipotassium phosphate
Bovine Serum Albumin

Beige to mid-brown, lyophilised.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers and future layers/breeders).

3.2 Indications for use for each target species

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

Onset of Immunity: 8 days after single-dose vaccination.

Duration of Immunity: 7 weeks after single-dose spray vaccination and
4 weeks after single-dose vaccination via drinking water.

3.3 Contraindications

None.

3.4 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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.
[2]Reactions are usually transient.

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 birds in lay and within 4 weeks before the start of the laying period.

3.8 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 vaccine, strain H120 (where authorised), 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.

3.9 Administration routes and dosage

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.

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

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

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 virus (Gumboro Disease).
The vaccine contains the live intermediate IBDV strain Lukert.

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 packaged for sale: 27 months.
Shelf life after reconstitution according to directions: 4 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Hydrolytic type I glass vial closed with type I butyl rubber stopper.

Pack sizes:
Box of 10 x 1,000 doses.

Box of 10 x 2,000 doses.
Box of 10 x 2,500 doses.
Box of 10 x 5,000 doses.
Box of 10 x 10,000 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)

VPA10387/091/001

8. DATE OF FIRST AUTHORISATION

18/09/2015

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

29/10/2026

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).