

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Bursine 2 Vaccine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances (per dose)

Infectious bursal disease virus strain Lukert $\geq 10^{4.3}$ TCID₅₀

Excipient(s)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Lyophilisate for suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens from one day of age.

4.2 Indications for use, specifying the target species

For the vaccination of broilers, rearing birds, future layers and breeding birds to reduce clinical signs caused by Gumboro Disease.

4.3 Contraindications

Do not vaccinate unhealthy birds.

4.4 Special warnings for each target species

Maternally-derived antibody (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 gumboro virus can breakthrough higher maternal antibody levels than the vaccine virus. Field infection is capable therefore of reaching birds before vaccine has a chance to take. Only use as part of a complete gumboro control programme involving hygiene, biosecurity, management, stocking density and disinfection, etc. Overwhelming levels of field virus may overcome vaccinal immunity.

The virus of the vaccine will spread to unvaccinated birds.

4.5 Special precautions for use

Special precaution for use in animals

None.

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.

4.6 Adverse reactions (frequency and seriousness)

Occasionally local and/or general reactions after administration of the vaccine can be observed. Reactions are usually transient.

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

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay or within 4 weeks before the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other, except Poulvac IB H120, administered to broilers at one day of age, where this vaccine is authorised. It is therefore recommended that no other vaccine than this should be administered within 7 days before or after vaccination with Poulvac Bursine 2 Vaccine.

4.9 Amounts to be administered and administration route

Future layers: 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: Vaccination may be carried out from one day of age by spray or drinking water.

Depending on the level of field virus present, repeat administration of the vaccine may be required. For the use of the vaccine in specific circumstances consult a Veterinary Surgeon or Fort Dodge Animal Health Technical Staff.

Nipple-drinking systems are not an appropriate method of vaccine delivery for 1-3 day old chicks.

Drinking water

1. 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.
2. 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.
3. 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 jug and stir well before mixing with more water in a two gallon bucket 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, eg 10 litres would be needed for 1,000 10 day old chickens.

Low-fat skimmed milk powder (ie <1% fat) may be added to the water (2–4 grams per litre) or skimmed milk (1 pint per 5 gallons of water) to increase the stability of the virus.

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.

4. Administer the dissolved vaccine to birds immediately after dilution.
5. Avoid exposure of the vaccine suspension to sunlight.
6. Water used for drinking water administration of a live virus vaccine must be non-chlorinated and contain as few as possible metal ions.

Coarse Spray

This method is for day old broiler chicks only and may be used in the hatchery or on farm.

Ensure that birds are neither overheated nor chilled following coarse spray.

1. Use a suitable sprayer and restrict use for vaccine only. If the Falcon 5S sprayer (5 litre capacity) is used replace the standard nozzle on this sprayer with a flat fan tip model –Lurmark tip –colour coded pink –reference no. 01F80. A black plastic lance adaptor will also be needed for this nozzle. The Cooper Pegler Knapsack sprayer, model CP3 is already equipped with the plastic lance adaptor, but the Lurmark flat fan tip nozzle should be fitted.
2. Pump sprayer up to 2 atmospheres and do not allow the pressure to drop below 1 atmosphere, when it should be recharged back to 2.
3. Use 1 litre (1,000 ml) of room temperature water per 1,000 chicks, allowing 15–20 seconds per 150 chick box. Spray the sides of the box first from a height of 12–18". Ensure no water spillage by rotating the sprayer end to spray into the box at each turn.

The operator may need to stand on a box to correctly spray two chick boxes at the right angle. Hold birds in boxes for approximately 30–45 minutes following vaccination. 500/750 ml has also been used with success. Ensure the temperature of the holding area is 70–80°F and draught free, to avoid chilling.

4. Whilst Poulvac Bursine 2 Vaccine is very resistant to low levels of chlorine, copper and organic matter etc, it is

advisable to use good quality water, eg deionised water. Treat water with milk powder, if necessary, but ensure that there are no particles which may block the spray nozzle.

Consult Fort Dodge Animal Health for further advice on the application of Poulvac Bursine 2 Vaccine to day old broiler chicks in an automated sealed cabinet in the hatchery.

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Infectious Bursal Disease Virus (Gumboro Disease).

ATC Vet code: QI01AD09

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pharmatone

Bacto-peptone

Sucrose

N-Z Amine

Glutamic acid sodium salt

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf-life

Shelf life as packaged for sale: 27 months

Shelf life after reconstitution: use immediately

6.4 Special precautions for storage

Store and transport refrigerated (2°C - 8°C).

Protect from light.

6.5 Nature and composition of immediate packaging

The lyophilised vaccine is bottled in Type I Borosilicate glass vials with fluted butyl rubber stoppers containing 1000, 2500, 5000 or 10,000 doses.

Pack sizes: 10 x 1000, 2500, 5000 and 10,000 doses.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 Noth Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/074/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th March 2009

10 DATE OF REVISION OF THE TEXT

June 2015