

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

POULVAC PABAC IV emulsion for injection in chickens, ducks and turkeys.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.5 ml

Active substances:

Pasteurella multocida, strain X-73 (serovar 1^{*}), inactivated min. 70% survival (chickens)^{* *}
Pasteurella multocida, strain P-1059 (serovar 3^{*}), inactivated min. 70% survival (turkeys)^{* *}
Pasteurella multocida, strain P-1662 (serovar 4^{*}), inactivated min. 70% survival (turkeys)^{* *}
Pasteurella multocida, strain CU (serovar 3x4^{*}), inactivated min. 70% survival (turkeys)^{* *}

^{*} according to Heddlestone classification

^{**} in vaccinated birds, following virulent challenge, according to Ph. Eur. 1945 requirements

Adjuvant:

Light liquid paraffin	0.325	ml
Sorbitan sesquioleate	0.025	ml
Polysorbate 80	0.004	ml

Quantity:

Excipients:

Formaldehyde	traces
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For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection.

White creamy emulsion, with no extraneous particles.

A separation of the emulsion can occur over time, leading to a biphasic appearance where the upper layer appears as white to an off-white milky suspension and the bottom layer appears as a grey to tan aqueous phase.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (future laying and future breeding hens), Ducks and Turkeys.

4.2 Indications for use, specifying the target species

In chickens (future laying and future breeding hens) and ducks:

- active immunization in order to reduce mortality caused by *Pasteurella multocida* serovar 1 (Heddleston classification).

Onset of immunity against serovar 1 is of 2 weeks from administration of the second dose.

Duration of immunity is of 16 weeks post basic vaccination (future laying and future breeding hens) or 9 weeks post basic vaccination (ducks).

In turkeys:

- active immunization in order to reduce mortality caused by *Pasteurella multocida* serovar 3, 4 and 3x4 (Heddleston classification).

Onset of immunity against serovars 3, 4 and 3x4 is of 2 weeks from administration of the second dose.

Duration of immunity is of 6 weeks post basic vaccination.

4.3 Contraindications

Do not vaccinate unhealthy birds.

Do not use in birds in lay.

4.4 Special warnings for each target species

No specific studies have been conducted in chickens and ducks to demonstrate efficacy of the vaccine against *Pasteurella multocida* serovars others than 1.

No specific studies have been conducted in turkeys to demonstrate efficacy of the vaccine against *Pasteurella multocida* serovars others than 3, 4 and 3x4.

No information is available on the possible interferences from the presence of maternal antibodies on the response to vaccination with Poulvac Pabac IV. It is therefore not recommended to use this vaccine in birds with maternal antibodies.

4.5 Special precautions for use

Special precautions for use in animals

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

TO THE USER :

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

TO THE PHYSICIAN :

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product that contains oil can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

In chickens: local reactions in the form of palpable swellings may be observed at the injection site in all birds. These swellings can be large (over 3 cm) and, in some birds (at least 5%), the local reactions may persist for more than 4 weeks after vaccination and the endpoint of these reactions is not known.

In turkeys: local reactions in the form of palpable swellings may be observed at the injection site in all birds. These swellings can be large (over 4.5 cm) and, in some birds (at least 10%), the local reactions may persist for more than 4 weeks after vaccination and the endpoint of these reactions is not known.

In ducks: local reactions in the form of palpable swellings may be observed at the injection site in all birds. These swellings can be large (over 6 cm) and, in some birds (at least 28%), the local reactions may persist for more than 4 weeks after vaccination and the endpoint of these reactions is not known.

A transient reduction in weight gain can be observed in chickens, ducks and turkeys for up to 4 weeks following vaccination.

These reactions do not require any particular treatment.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay.

4.8 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. 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.

4.9 Amounts to be administered and administration route

Administration

One dose of 0.5 ml by subcutaneous route only (at the base of the neck).

Before administration, allow the vaccine to warm to room temperature and shake well.

A separation of the emulsion can occur over time, leading to a biphasic appearance. The upper layer represents the majority of the finished product and appears as a white to an off-white milky suspension. The bottom phase is grey to tan and appears more aqueous.

Gentle shaking of the bottle will allow the product to return to a homogeneous appearance. This minor separation has no effect on the safety or efficacy of the product.

Administer under aseptic conditions.

Vaccination schedule

Chickens (future laying and future breeding hens) :

First injection at 6 weeks.

Booster : 4 weeks later.

Ducks :

First injection at 3 weeks.

Booster : 3 weeks later.

Turkeys :

First injection at 6 weeks.

Booster : 4 weeks later.

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

Adverse effects observed are similar to those mentioned in paragraph 4.6 after administration of a double dose. However, persistent large size local reactions are obtained in a higher proportion of birds after administration of double dose.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The vaccine induces active immunity against serovars 1, 3, 4 and 3x4 of *Pasteurella multocida*.

ATC Vet code : QI01AB02
Inactivated bacterial vaccines.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin
Sorbitan sesquioleate
Polysorbate 80
Formaldehyde
Sodium chloride
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale : 2 years.
Use the entire content of the bottle immediately after broaching.

The use of a closed multi-dose injection system is recommended for administration of the product to minimise the risk of contamination. Any unused product must be discarded within 3 hours of broaching

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Nature of the primary containers :

High density polyethylene bottle.

Chlorobutyl stopper

Aluminium cap.

Packaging :

Carton box of 1 bottle of 1000 doses.

Carton box of 10 bottles of 1000 doses.

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with the local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/078/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th July 2012

10 DATE OF REVISION OF THE TEXT

December 2013