

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Past M.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Ingredients</u>	<u>Per dose (0.5ml)</u>
<i>Pasteurella multocida</i> strain X-73	$3.75 \times 10^8 - 1 \times 10^9$ CFU*
<i>Pasteurella multocida</i> strain P-1059	$5.02 \times 10^8 - 1 \times 10^{10}$ CFU*
<i>Pasteurella multocida</i> strain P-1662	$3.75 \times 10^8 - 1 \times 10^9$ CFU*

*CFU: Colony Forming Units

Constituents

Sterile Saline	0.235000 ml
Formalin Solution	0.000875 ml
Tween-80	0.003000 ml
White Oil	0.240000 ml
Arlacel-83	0.010000 ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

Inactivated, liquid, adjuvanted bacterin suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens and turkeys.

4.2 Indications for use, specifying the target species

To reduce clinical signs and mortality of Fowl Cholera (Pasteurellosis) infection.

The duration of immunity is 16 weeks

4.3 Contraindications

Do not administer via the intramuscular route

Refer to section 4.4 and 4.7.

4.4 Special warnings for each target species

Vaccinate only healthy animals.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the 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 insert 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 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.

4.6 Adverse reactions (frequency and seriousness)

The vaccine can cause local and/or general reactions.

Local reactions present as a slight swelling at the injection site following vaccination, but are resolved by 8 weeks after the second vaccination. General reactions may be observed as a slight and transient weight gain depression with complete recovery by six weeks post-vaccination.

4.7 Use during pregnancy, lactation or lay

Not to be used for 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. It is therefore recommended that no other vaccines should be administered within 7 days before or after vaccination with the product.

4.9 Amounts to be administered and administration route

Basic Vaccination Scheme

Dose: 0.5ml to chickens from 12 weeks of age and turkeys from 8 weeks of age.

Administration: By subcutaneous injection in the neck

Dosage schedule: Vaccination consists of two doses

Vaccination scheme: 1 dose to chickens from 12 weeks or turkeys from 8 weeks of age. A second vaccination must be administered 4 to 5 weeks after the first vaccination.

Shake the vial well before use.

Use sterile needles and syringes and observe aseptic precautions.

The proper site for inserting the needle of the syringe is at a point on the middle of the back of the neck, midway between the head and the body. In turkeys, the midway point is in the feathered area of the neck.

Lift the skin at the vaccination site with the thumb and forefinger. Insert the entire length of the needle just under the skin in a direction toward the base of the neck (away from the head). The needle should enter the skin in a straight line with the neck.

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

The vaccine is shown to be safe at a double dose before release.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Fowl Cholera (Pasteurellosis).

ATC Vet code: QI01AB02

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formalin solution (35 % Formaldehyde)

Sterile saline

Tween-80

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf-life

Shelf-life as package for sale: 22 months

Shelf-life after opening: Use immediately.

6.4 Special precautions for storage

Store at +2°C to +8°C. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Bottles: Polyethylene bottles, sterile, 120ml (200 doses) and 500ml (1000 doses).

Stoppers: Flat, butyl rubber stoppers, sterile, 20mm or 30mm.

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 national requirements.

7 MARKETING AUTHORISATION HOLDER

Fort Dodge Animal Health Limited
Flanders Road
Hedge End
Southampton
SO30 4QH,
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA No. 10861/57/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd March 2003