Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac MG.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml dose contains:

Active substance:

Mycoplasma gallisepticum strain R-980 ≥ 1,000 MGCFU*

*MGCFU = *Mycoplasma gallisepticum* Colony Forming Units

Adjuvants:

White oil 0.36 ml

Excipients:

Formaldehyde Solution (37 %) 0.001 ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens and turkeys from 3 weeks of age.

4.2 Indications for use, specifying the target species

For active immunisation of chickens and turkeys to reduce mortality and clinical signs of Mycoplasma gallisepticum for up to 15 weeks.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Avoid stress in the birds around the time of vaccination.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

On completion, operators should wash and disinfect hands in an approved disinfectant.

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 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)

None.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay and/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 this product.

4.9 Amounts to be administered and administration route

Dose: 0.5 ml

Administration: Poulvac MG can be administered subcutaneously or intramuscularly.

Vaccination Scheme: Birds should be vaccinated with two doses of Poulvac MG with a 4 week interval between each dose.
The vaccination scheme should be completed 4 weeks prior to the point of lay.

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

When an overdose is given, palpable granulomatous injection site reactions may be observed in a minority (<10%) of birds for up to 21 days after vaccine administration.

4.11 Withdrawal Period(s)

Meat and eggs: 6 weeks.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against *Mycoplasma gallisepticum*.

ATCvet Code: QI01AB03

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White oil
Sorbitan sesquioleate
Polysorbate 80
Phosphate Buffered Saline
Formaldehyde Solution (37%)

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 22 months
Shelf-life after first opening the immediate packaging: Use immediately.

6.4 Special precautions for storage

Store in a refrigerator (2^{o}C - 8^{o}C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Containers: Polyethylene bottles. Volume: 500-ml.

Closures: sterile 30-mm flat butyl rubber stoppers.

Presented in packs of 10 vials x 1000 dose.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland
Trading as Pfizer Animal Health,
Ringaskiddy,
Co. Cork,
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/179/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8th October 2008

10 DATE OF REVISION OF THE TEXT

14th May 2010

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Poulvac MG is restricted or prohibited in Ireland pursuant to national animal health policy.

Any person intending to import, sell supply and/or use Poulvac MG must consult the Department of Agriculture on the current vaccination policies prior to import, sale, supply and/or use.