Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac M. hyo emulsion for injection for pigs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Inactivated whole culture of *Mycoplasma hyopneumoniae*, J Strain, Isolate B-3745 grown in liquid medium

One dose of 2 ml vaccine contains:

Active substance:

***Mycoplasma hyopneumoniae*:**	**≥**	**1 : 80***

*antibody titre elicited with ½ dose (rabbits/ELISA assay)

Adjuvant:

Montanide ISA 708:	1.30 ml (65 %)

Excipients

For a complete list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Emulsion for injection. White opaque emulsion.

4 CLINICAL PARTICULARS

4.1 Target Species

Fattening pigs.

4.2 Indications for use, specifying the target species

For active immunisation of pigs from 3 weeks of age to reduce lung lesions following infection with *Mycoplasma hyopneumoniae.*

Onset of protection occurs by two weeks post vaccination and lasts for at least 118 days.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only clinically healthy animals.
In case of anaphylactic reactions, the administration of epinephrine is recommended.
The application of the vaccine should be performed according to the requirements of Good Veterinary Practice.
Injections with Ingelvac M. hyo done improperly can cause injection site lesions, such as granulomas or abscesses.

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

Self injection may result in pain and swelling and may persist several days. In case of accidental self injection of vaccine, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Depression and reduction of appetite may occur after administration. These clinical signs generally disappear within a few days.
Swelling of about two centimetres in diameter, which may be of hard consistency, may be observed at the site of injection in about 2.4 % of the cases. These swellings will disappear within one to two days.
In very rare cases granulomatous reactions at the injection site have been observed at the slaughterhouse, which were mainly caused by an improper injection technique (see 4.5).

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation.

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 14 days before or after vaccination with this product.

4.9 Amounts to be administered and administration route

Warm to room temperature prior to use. The minimum needle diameter recommended is 1.2 mm.
Shake well before use.
The vaccination dose is 2 ml, irrespective of body weight.
A single dose should be administered by deep intramuscular injection in the neck to pigs of three to ten weeks of age.

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

No adverse reactions other than those listed in section 4.6 have been observed following administration of twice the recommended dose.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The vaccine is designed to stimulate the development of an active immune response to *Mycoplasma hyopneumoniae.*
ATC Vet code: QI09AB13 (Mycoplasma vaccine).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montanide ISA 708
Hank's Balanced Salt Solution
Water for Injection in bulk

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: 2 years (100 ml), 1 year (20 ml).
Shelf-life after first opening the immediate packaging: Use immediately after opening.

6.4 Special precautions for storage

Store and transport refrigerated (+ 2 °C - + 8 °C).
Do not freeze.

6.5 Nature and composition of immediate packaging

High density polyethylene vial of 20 ml (10 doses) or 100 ml (50 doses), closed with a chlorobutyl stopper with lacquered aluminium seal in cardbox boxes. Not all pack sizes may be marketed.

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

Boehringer Ingelheim Limited
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Berkshire RG12 8YS
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10007/038/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18th January 2007

10 DATE OF REVISION OF THE TEXT

27th July 2007

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