

Operator Warnings: Ensure that the method of restraint, handling and administration, e.g. by the use of guarded needles, minimises the risk of accidental injection/self injection.

In case of accidental self injection of vaccine, seek medical advice immediately and show the package insert to the physician.

Disposal Advice: Empty vaccine containers and any unused material shall be discarded according to national regulations.

Withdrawal period
Zero days

For animal treatment only.

Pharmaceutical Precautions:

Store and transport between +2°C and +8°C
Do not freeze.

Use immediately after opening

Keep out of reach and sight of children.

For veterinary prescription only

Legal Category: POM

Package Quantities:

High density polyethylene vial of 20ml (10 doses) and 100ml (50 doses), closed with a chlorobutyl stopper with lacquered aluminium seal.

Marketing Authorisation numbers:
Vm 00015/4067

Marketing Authorisation holder

Boehringer Ingelheim Limited
Ellesfield Avenue

Bracknell
Berkshire

RG12 8YS
UK

Manufacturer:

Boehringer Ingelheim Vetmedica, Inc
St Joseph, Missouri, 64506-2002, USA
US Veterinary License No 124

Date of preparation:

This data sheet was prepared in March 2004

Ingelvac M hyo Data Sheet

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Ingelvac M hyo
Mycoplasma hyopneumoniae

Presentation

Emulsion for injection for fattening pigs.

Inactivated whole culture of *Mycoplasma hyopneumoniae*, J strain, isolate B-3745 grown in liquid medium.

One dose of two ml vaccine contains – *before inactivation* : Min. antigen: 3.0 x 10⁸ CCU*, max. antigen 6.0 x 10⁸ CCU*
* : Colour Changing Units
after *Inactivation* - *Mycoplasma hyopneumoniae* ≥ 1 : 80 antibody titre elicited with ½ dose (rabbits/ELISA assay)

Adjuvant : Montanide ISA 708 : 1.30ml (65%)

Uses

For active immunisation of pigs from three 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.

Dosage and administration

Warm to room temperature and shake well prior to use. The minimum needle diameter recommended is 1.2 mm. 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. Avoid the introduction of contamination during use.

Contra-indications, warnings etc

Depression and reduction of appetite may occur after administration. These symptoms generally disappear within a few days. Swellings 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.

Do not mix with any other vaccine/immunological product.

Vaccinate only clinically healthy animals.

In the case of anaphylactic reactions, the administration of epinephrine is recommended.

Do not use during pregnancy and lactation.

No information is available on the safety and efficacy of 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 the product.