

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac® M. hyo, emulsion for injection for pigs

STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated whole culture of *Mycoplasma hyopneumoniae*, J Strain, Isolate B-3745.

One dose of 2 ml vaccine contains:

Active substance

Before inactivation:

Mycoplasma hyopneumoniae: Minimum antigen 3.0×10^8 CCU*
Maximum antigen 6.0×10^8 CCU*
*: Colour Changing Units before inactivation

After inactivation:

Mycoplasma hyopneumoniae: $\geq 1 : 80^*$
antibody titre elicited with $\frac{1}{2}$ dose
(rabbits/ELISA assay)

Adjuvant

Montanide ISA 708: 1.30 ml (65 %)

PHARMACEUTICAL FORM

Emulsion for injections

PACKAGE SIZE

- 20 ml (10 doses)
- 100 ml (50 doses)

TARGET SPECIES

Fattening pigs

INDICATION

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

METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Single vaccination dose: 2 ml , intramuscular.
Read the package leaflet before use.

WITHDRAWAL PERIOD

Zero days.

SPECIAL WARNING(S), IF NECESSARY

In case of accidental self injection of vaccine, seek medical advice immediately and show the package insert [or the label](#) to the physician.

EXPIRY DATE

EXP: (month/year)

Use immediately after opening

SPECIAL STORAGE CONDITIONS

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

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

[Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.](#)

THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

MARKETING AUTHORISATION NUMBER

Vm 08327/4295

MANUFACTURER'S BATCH NUMBER

Batch No.: (number)

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac® M. hyo

STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 2 ml vaccine contains:

Active substance

Before inactivation:

Mycoplasma hyopneumoniae: Minimum antigen 3.0×10^8 CCU*
Maximum antigen 6.0×10^8 CCU*
*: Colour Changing Units before inactivation

After inactivation:

Mycoplasma hyopneumoniae: $\geq 1 : 80^*$
antibody titre elicited with $\frac{1}{2}$ dose
(rabbits/ELISA assay)

Adjuvant

Montanide ISA 708: 1.30 ml (65 %)

PHARMACEUTICAL FORM

Emulsion for injections

PACKAGE SIZE

- 20 ml (10 doses)
- 100 ml (50 doses)

TARGET SPECIES

Fattening pigs

INDICATION(S)

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

METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Single vaccination dose: 2 ml , intramuscular.
Read the package leaflet before use.

WITHDRAWAL PERIOD

Zero days

SPECIAL WARNING(S), IF NECESSARY

In case of accidental self injection of vaccine, seek medical advice immediately and show the package insert [or the label](#) to the physician.

EXPIRY DATE

EXP: (month/year)
Use immediately after opening

SPECIAL STORAGE CONDITIONS

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

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

[Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.](#)

THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

MARKETING AUTHORISATION NUMBER

Vm 08327/4295

MANUFACTURER'S BATCH NUMBER

Batch No: (number)

PACKAGE LEAFLET

Ingelvac® M. hyo

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturing authorisation holder responsible for batch release

Boehringer Ingelheim Vetmedica GmbH

Binger Strasse 173

55316 Ingelheim am Rhein

GERMANY

NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac® M. hyo, [emulsion for injection for pigs](#)

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Inactivated whole culture of *Mycoplasma hyopneumoniae*, J Strain, Isolate B-3745

One dose of 2 ml vaccine contains:

Active substance

Before inactivation:

<i>Mycoplasma hyopneumoniae</i> :	Minimum antigen 3.0 x 10 ⁸ CCU*
	Maximum antigen 6.0 x 10 ⁸ CCU*
	*: Colour Changing Units before inactivation

After inactivation:

<i>Mycoplasma hyopneumoniae</i> :	≥ 1 : 80*
	antibody titre elicited with ½ dose (rabbits/ELISA assay)

Adjuvant

Montanide ISA 708:	1.30 ml (65 %)
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INDICATIONS

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.

CONTRAINDICATIONS

None known.

ADVERSE REACTIONS

Depression and reduction of appetite may occur after administration. These symptoms 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.

TARGET SPECIES

Fattening pigs.

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

ADVICE ON CORRECT ADMINISTRATION

Warm to room temperature prior to use.

The minimum needle diameter recommended is 1.2 mm.

Shake well before use.

WITHDRAWAL PERIOD

Zero days.

SPECIAL STORAGE PRECAUTIONS

Store and transport **refrigerated** (+ 2°C - + 8°C)

Use immediately after opening of the bottle.

Do not use after the expiry date stated on the bottle.

Do not freeze.

Keep out of the reach and sight of children.

SPECIAL WARNINGS

Vaccinate only clinical healthy animals.
Do not use during pregnancy and lactation.
In case of anaphylactic reactions, the administration of epinephrine is recommended.
In case of accidental self injection of vaccine, seek medical advice immediately and show the package insert or labelling to the physician.
Do not mix with any other vaccine/immunological product.
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 the product.
For animal treatment only.

SPECIAL PRECAUTIONS for THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

XX.XX.XXXX

OTHER INFORMATION

Not all package sizes may be marketed.

Approved: 07 November 2018

