

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 ml; 50 ml, 100 ml, 250 ml cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac MycoFLEX suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (1 ml) contains: inactivated *Mycoplasma hyopneumoniae*, J Strain
Carbomer

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 ml (10 doses)
50 ml (50 doses)
100 ml (100 doses)
250 ml (250 doses)
12 x 10 ml (10 doses)
12 x 50 ml (50 doses)
12 x 100 ml (100 doses)
12 x 250 ml (250 doses)

5. TARGET SPECIES

Pigs (fattening pigs or future breeders until first reproductive service).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Single intramuscular injection of 1 ml.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4296

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

<https://youtu.be/xt9tJ8GRMXQ>



PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml, 250 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac MycoFLEX suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (1 ml) contains: inactivated *Mycoplasma hyopneumoniae*, J Strain
Carbomer

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml (100 doses)
250 ml (250 doses)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Single IM injection of 1 ml.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4296

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml, 50 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac MycoFLEX suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (1 ml) contains: inactivated *Mycoplasma hyopneumoniae*, J Strain
Carbomer

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml (10 doses)

50 ml (50 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

Once opened, use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Ingelvac MycoFLEX suspension for injection for pigs

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

Marketing authorisation holder and manufacturer responsible for batch release

UK:

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

Manufacturer responsible for batch release

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac MycoFLEX suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

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

Each dose (1 ml) of inactivated vaccine contains:

Mycoplasma hyopneumoniae: \geq 1 RP*

* Relative potency (ELISA test) by comparison with a reference vaccine.

Adjuvant: Carbomer

Clear to slightly opalescent, pink to brown suspension for injection.

4. INDICATIONS

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

Onset of immunity: 2 weeks post vaccination

Duration of immunity: at least 26 weeks.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Adverse reactions are very rare (less than 1 animal in 10,000 animals, including isolated reports):

- Anaphylactic-type reactions may occur and should be treated symptomatically (e.g. epinephrine)
- transient swelling up to 4 centimetres in diameter, sometimes associated with redness of the skin, may be observed at the injection site. These swellings may last up to 5 days.
- a transient mean increase in rectal body temperature of about 0.8 °C lasting up to 20 hours after vaccination may be observed.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (fattening pigs or future breeders until first reproductive service).

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Single intramuscular (IM) injection of one dose (1 ml), preferably in the neck of pigs from 3 weeks of age.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

Avoid introduction of contamination during use.

Avoid multiple vial broaching.

Vaccine devices should be used in accordance with the device instructions provided by the manufacturer. After correct handling in accordance with the mixing instructions no leakage should occur. In case of any leakage or incorrect handling of the product the bottle should be discarded.

Use equipment that prevents flush back of the veterinary medicinal product.

When mixed with Ingelvac CircoFLEX:

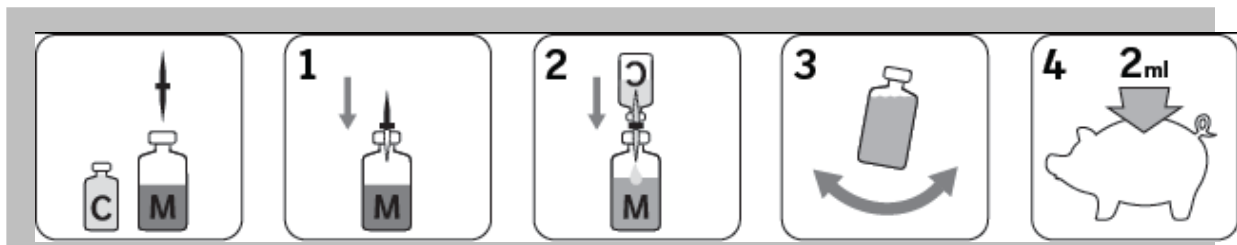
- Vaccinate only pigs from 3 weeks of age.

When mixed with Ingelvac CircoFLEX the following equipment should be used:

- Use the same volumes of Ingelvac CircoFLEX and Ingelvac MycoFLEX.
- Use a pre-sterilized transfer needle. Pre-sterilized transfer needles (CE certified) are commonly available via medical equipment suppliers.

To ensure correct mixing follow the steps as described below

1. Connect one end of the transfer needle to the vaccine bottle of Ingelvac MycoFLEX.
2. - Connect the opposite end of the transfer needle to the vaccine bottle of Ingelvac CircoFLEX.
- Transfer the Ingelvac CircoFLEX vaccine into the vaccine bottle of Ingelvac MycoFLEX. If needed, gently press the vaccine bottle of Ingelvac CircoFLEX to facilitate the transfer.
- After the transfer of the full content of Ingelvac CircoFLEX, disconnect and discard transfer needle and empty vaccine bottle of Ingelvac CircoFLEX.
3. To ensure appropriate mixing of the vaccines, gently shake the vaccine bottle of Ingelvac MycoFLEX until the mixture is of uniform orange to reddish colour. During vaccination the uniformity of the coloured mixture should be monitored and maintained by continuous agitation.
4. Administer one single injection dose (**2 ml**) of the mixture intramuscularly per pig, irrespective of body weight. For administration, vaccine devices should be used in accordance with the device instructions provided by the manufacturer.

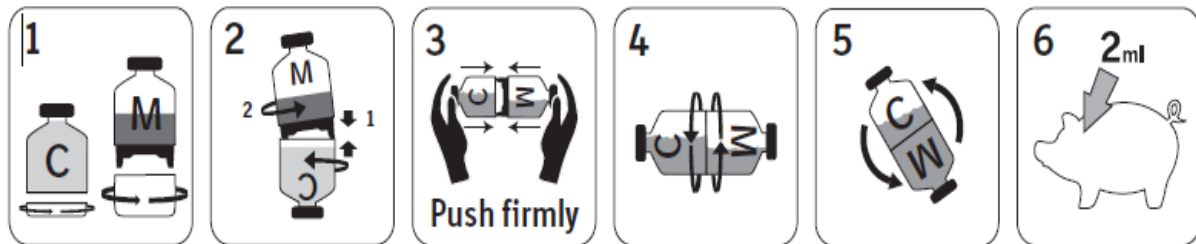


To ensure correct mixing with the TwistPak bottles follow the steps as described below or using the <https://youtu.be/xt9tJ8GRMXQ>



1. **Twist and remove** the red base of the bottle of Ingelvac MycoFLEX to uncover the connection system. The red base could be used upside down as a stand to position of the Ingelvac MycoFLEX bottle upside down.
Twist and remove the green base of the Ingelvac CircoFLEX bottle.
2. **Rotate and align** the connection ends of the two bottles until they engage.
3. **Firmly push** the bottles together until they touch one another completely.
A click confirms that the bottles are engaged.

4. **Twist** the two vaccine bottles clockwise to complete the coupling of both bottles.
5. To ensure appropriate mixing, slowly **invert** the locked bottles until the mixture is of uniform orange to reddish color. During vaccination, the uniformity of the coloured mixture should be monitored and maintained by continuous agitation.
6. Administer one single injection dose (**2 ml**) of the mixture intramuscularly per pig, irrespective of body weight. For administration, vaccine devices should be used in accordance with the device instructions provided by the manufacturer.



Use the entire vaccine mixture immediately after mixing. Any unused mixture or waste material should be disposed of in accordance with local requirements.

The package leaflet of Ingelvac CircoFLEX should also be consulted before the administration of the mixed product.

For any further information please contact the local representative of the marketing authorisation holder.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after EXP.

Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals

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

Pregnancy and lactation

Not applicable.

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Boehringer Ingelheim's Ingelvac CircoFLEX and administered at one injection site.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):

Following the administration of a 4-fold overdose of vaccine no adverse reactions other than those described under section Adverse Reactions have been observed.

Incompatibilities

Do not mix with any other veterinary medicinal product, except with Boehringer Ingelheim's Ingelvac CircoFLEX.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally.

15. OTHER INFORMATION

This vaccine is designed to stimulate the development of an active immune response to *Mycoplasma hyopneumoniae* in pigs.

Either 1 or 12 high density polyethylene bottles of 10 ml (10 doses in 30 ml bottles), 50 ml (50 doses in 120 ml bottles), 100 ml (100 doses in 250 ml bottles), or 250 ml (250 doses in 500 ml bottles) vaccine packed in a cardboard box.

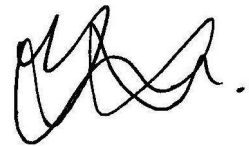
Either 1 or 12 high density polyethylene TwistPak bottles of 10 ml (10 doses in 30 ml bottles), 50 ml (50 doses in 50 ml bottles), 100 ml (100 doses in 100 ml bottles) or 250 ml (250 doses in 250 ml bottles) vaccine packed in a cardboard box.

Not all pack sizes may be marketed.

UK, FR:

Ingelvac MycoFLEX is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, used under licence.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 29 July 2021