SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac MycoFLEX suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Each dose (1 ml) of inactivated vaccine contains:

Active substance:
Mycoplasma hyopneumoniae: ≥ 1 RP*
* Relative potency (ELISA test) by comparison with a reference vaccine.

Adjuvant:
Carbomer: 1 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

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

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 immunity: 2 weeks post vaccination
Duration of immunity: at least 26 weeks.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
In case of anaphylactic-type reactions, the administration of epinephrine is recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 four centimetres in diameter, sometimes associated with redness of the skin, may be observed at the injection site. These swellings may last up to five 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).

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 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.

4.9 Amounts to be administered and administration route

Shake well before use.
Single intramuscular injection of one dose (1 ml), preferably in the neck of pigs from 3 weeks of age.
Avoid introduction of contamination during use.

Avoid multiple 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:
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.

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

Following the administration of a 4-fold overdose of vaccine no adverse reactions other than those described under section 4.6 have been observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Suidae, inactivated bacterial vaccines
ATC vet code: QI09AB13

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Sodium chloride
Water for injection

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 10 hours

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box with 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 with a chlorobutyl stopper and lacquered aluminium seal.

Cardboard box with 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 with a chlorobutyl stopper and lacquered aluminium seal.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4296

9. DATE OF FIRST AUTHORISATION

04 August 2009

10. DATE OF REVISION OF THE TEXT

July 2021

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