A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (FLEXI-PACK)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

M+PAC

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active ingredients:	Quantity per 1ml volume:
Mycoplasma hyopneumoniae, inactivated	≥ 1.47 RPU (*)
Light mineral oil	0.134 ml
Aluminium (as hydroxide)	1.0 mg
Thiomersal	0.10 mg
Excipients	qs 1 ml

(*) Relative Unit defined against a reference vaccine

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

50 ml
100 ml
200 ml

5. TARGET SPECIES

Pig (fattening pigs, from 7 days of age)

6. INDICATION(S)

For the active immunization of pigs in order to reduce frequency and severity of lung lesions caused by *Mycoplasma hyopneumoniae.*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection
Shake well before use
Read the package leaflet before use

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – see package leaflet before use.

10. EXPIRY DATE

Expiry date: {MM-YYYY}
In use shelf life: 8 hours

11. SPECIAL STORAGE CONDITIONS

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

12. 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.

13. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

15. MARKETING AUTHORISATION NUMBER

Vm 01708/5100

16. MANUFACTURER'S BATCH NUMBER

Lot No. {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

M+PAC

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active ingredients:	Quantity per 1 ml volume:
Mycoplasma hyopneumoniae, inactivated	≥ 1.47 RPU (*)
Light mineral oil	0.134 ml
Aluminium (as hydroxide)	1.0 mg
Thiomersal	0.10 mg
Excipients	qs 1 ml

(*) Relative Unit defined against a reference vaccine

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

1 x 50 ml, 2 x 50 ml, 5 x 50 ml, 10 x 50 ml
1 x 100 ml, 2 x 100 ml, 5 x 100 ml, 10 x 100 ml
1 x 200 ml, 2 x 200 ml, 5 x 200 ml, 10 x 200 ml

5. TARGET SPECIES

Pig (fattening pigs, from 7 days of age)

6. INDICATION(S)

For the active immunisation of pigs in order to reduce frequency and severity of lung lesions caused by *Mycoplasma hyopneumoniae.*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection
Shake well before use
Read the package leaflet before use

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental injection is dangerous – see package leaflet.

10. EXPIRY DATE

Expiry date: {MM-YYYY}
In use shelf life: 8 hours

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material in accordance with national requirements

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 REACH AND SIGHT OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/5100

17. MANUFACTURER'S BATCH NUMBER

Lot No. {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

M+PAC

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

MARKETING AUTHORISATION HOLDER:

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

MANUFACTURER FOR THE BATCH RELEASE:

Burgwedel Biotech GmbH
Im Langen Felde
30938 Burgwedel
Germany

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

M+PAC

3. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Active ingredients:	Quantity per 1ml volume:
Mycoplasma hyopneumoniae, inactivated	≥ 1.47 RPU (*)
Light mineral oil	0.134 ml
Aluminium (as hydroxide)	1.0 mg
Thiomersal	0.10 mg
Excipients	qs 1ml

(*) Relative Unit defined against a reference vaccine

White liquid emulsion

4. INDICATION(S)

For the active immunisation of pigs in order to reduce frequency and severity of lung lesions caused by *Mycoplasma hyopneumoniae.*

For the active immunisation of pigs in order to reduce frequency and severity of lung lesions caused by Mycoplasma hyopneumoniae.

For vaccination with 2 doses of 1 ml given 2 – 4 weeks apart, protection has been demonstrated 35 days post initial dose and the duration of immunity is at least 6 months. In field studies, only seroconversion has been demonstrated in pigs receiving two 1 ml doses.

For vaccination with 1 dose of 2 ml, protection has been shown 24 days after vaccination and duration of immunity is at least 6 months after vaccination.

5. CONTRAINDICTIONS

None

6. ADVERSE REACTIONS

A small proportion of pigs may experience polypnoea and dizziness within 5 – 10 minutes of first vaccination. This resolves within 4 hours without treatment or further adverse effect on the animal. An increase in respiration rate may also occur in a small proportion of piglets within a few hours of injection with either a 1 or 2 ml dose. Hyperthermia may occur in a small proportion of piglets given 1 ml (<39.8 °C) and a higher proportion given 2 ml (mean 40.2 °C), returning to normal within 24 – 48 hours. Adverse reactions are uncommon after the second vaccination. Local reactions at the injection site are common but are restricted to a slight swelling (<2 cm diameter) which disappears within 24 – 48 hours of injection. In rare cases a granuloma may occur in the muscle at the injection site which may last over 21 days but resolves over time. Correct aseptic technique will reduce this possibility further.
[These observations were made during small scale laboratory studies and field trials].

In rare cases, emesis, dyspnoea, ataxia, muscle tremor, convulsion, diarrhoea, lethargy or anorexia may be observed following vaccination.

In the event of hypersensitivity reactions (shock), appropriate treatment such as adrenaline should be administered without delay.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pig, (fattening pigs, from 7 days of age)

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

Dose:

Pigs from 7 days of age: 1 ml. Two doses should be administered 14 – 28 days apart.

Pigs from 21 days of age: single dose of 2 ml or two doses of 1 ml administered 14 – 28 days apart.

Administration: By intramuscular injection. The recommended site is the side of the neck and for two dose administration use alternate sides.

The bottle should be well shaken before any vaccine is withdrawn.

9. ADVICE ON CORRECT ADMINISTRATION

There is no need to warm the vaccine before use.

Syringes and needles must be sterilised before use and the injection should be made through an area of clean, dry skin taking precautions against contamination. Follow aseptic procedures.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.

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

Do not use after the expiry date stated on the bottle.
Shelf-life after first opening the immediate packaging: 8 hours.

12. SPECIAL WARNING(S)

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Operator warning: This product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare case could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician: This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

The use is not recommended during pregnancy or lactation.

No information is available on the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccine should be administered within 14 days before or after vaccination with this product.

Do not mix with any other vaccine or immunological product.

FOR ANIMAL TREATMENT ONLY

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIAL, IF ANY

Any unused product or waste material should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2023

15. OTHER INFORMATION

Pack sizes:

1 x 50 ml, 2 x 50 ml, 5 x 50 ml, 10 x 50 ml
1 x 100 ml, 2 x 100 ml, 5 x 100 ml, 10 x 100 ml
1 x 200 ml, 2 x 200 ml, 5 x 200 ml, 10 x 200 ml

Not all pack sizes may be marketed.

Approved 16 January 2024