Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

M+PAC

ThoroVAX (in DK, SE, EE, LT, LV)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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 1ml

For full list of excipients, see section 6.1.

(*) Relative Unit defined against a reference vaccine

3 PHARMACEUTICAL FORM

Emulsion for injection.

[White liquid emulsion]

4 CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

For the active immunization 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.

4.3 Contraindications

None.

4.4 Special warnings

Piglets vaccinated from 7 days of age :
Under laboratory conditions, piglets from 4 weeks of age after administration of 2 doses of 1 ml at 2-4 weeks interval produced a protective immune response in the presence of passively acquired antibodies. Furthermore, under field conditions piglets from 6 days old produced a serological response in the presence of such antibodies.

Piglets vaccinated from 21 days of age :
Analysis of laboratory tests after the administration of a single 2 ml dose have shown no correlation between antibody level of maternal origin at the time of vaccination and the efficacy of vaccination; this suggests that maternally derived immunity in piglets does not interfere with vaccination.

4.5 Special precautions for use

Special precautions for use in animals:

Not applicable.

Special precautions to be taken by the person administering the medicinal product to animals:

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

To the user: 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.

4.6 Adverse reactions (frequency and seriousness)

A small proportion of pigs may experience polypnea 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.

4.7 Use during pregnancy or lactation

The use is not recommended during pregnancy or lactation.

4.8 Interactions with other medicinal products and other forms of interaction

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 this product.

4.9 Amounts to be administered and administration route

Pigs from 7 days of age: 1 dose of 1 ml. This 1 ml dose should be repeated after 14 – 28 days.

Pigs from 21 days of age : 1 single dose of 2 ml or 2 doses of 1 ml administered at an interval of 14-28 days.

Vaccinate pigs by the intramuscular route, preferably on alternate sides of the neck.

The vial should be well shaken before withdrawing a dose. There is no need to warm the vaccine before use. Syringes and needles must be sterile before use. The injection should be performed in a clean and dry skin area, taking appropriate precaution to avoid contamination.
Follow usual aseptic procedures.

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

No additional undesirable side effects other than those mentioned in section 4.6 have been observed after the administration of 4ml of the vaccine.

4.11 Withdrawal period(s)

Zero days.

5 IMMUNOLOGICAL PROPERTIES

ATC vet code: QI09AB-13
The vaccine contains the strain ATTC#25934 of *Mycoplasma hyopneumoniae* inactivated with bromoethylenimine and adjuvanted. The vaccine induces an active immunity against *M. hyopneumoniae* as demonstrated by virulent challenge.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan oleate
Polysorbate

Ethyl alcohol
Glycerol
Sodium chloride (0.85% w/v)

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

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: 8 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Nature of primary packaging:
High density polyethylene bottle closed with Teflon coated bromobutylrubber stoppers or PET bottles closed with nitrile rubber stoppers
Rubber stopper: type I
Aluminium seal

Presentations for sale:
Box of 1 bottle of 50 ml
Box of 2 bottles of 50 ml
Box of 5 bottles of 50 ml
Box of 10 bottles of 50 ml
Box of 1 bottle of 100 ml
Box of 2 bottles of 100 ml
Box of 5 bottles of 100 ml
Box of 10 bottles of 100 ml
Box of 1 bottle of 200 ml
Box of 2 bottles of 200 ml
Box of 5 bottles of 200 ml
Box of 10 bottles of 200 ml

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

7 MARKETING AUTHORISATION HOLDER

(Specific to each CMS)

8 MARKETING AUTHORISATION NUMBER(S)

(Specific to each CMS)

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

First Authorisation: 16th November 2001 / Renewed Authorisation (M.R.): 31st March 2007

10 DATE OF REVISION OF THE TEXT

July 2014

PROHIBITION OF SALE, SUPPLY AND/OR USE:

Not applicable.

A. LABELLING

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

M+PAC / ThoroVAX

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 1ml

(*) Relative Unit defined against a reference vaccine

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

50ml
100ml
200ml

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 (+2ºC to +8ºC)
Do not freeze
Protect from light

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

Specified for each CMS

16. MARKETING AUTHORISATION NUMBER

Unique for each CMS

17. MANUFACTURER'S BATCH NUMBER

Lot No. {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

M+PAC / ThoroVAX

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 1ml

(*) Relative Unit defined against a reference vaccine

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

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

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

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 (+2ºC to +8ºC.)
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

Specified for each CMS

16. MARKETING AUTHORISATION NUMBER

Unique for each CMS

17. MANUFACTURER'S BATCH NUMBER

Lot No. {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

M+PAC / ThoroVAX

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

Marketing Authorisation Holder:

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

(Complete nationally)

Manufacturer for the batch release:
Burgwedel Biotech GmbH
Im Langen Felde 5
D-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 / ThoroVAX

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	0.10mg
Excipients	qs 1ml

(*) Relative Unit defined against a reference vaccine

White liquid emulsion

4. INDICATION(S)

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

For vaccination with two doses of 1ml given 14 – 28 days apart, protection has been demonstrated 35 days post initial dose. The duration of immunity is at least 6 months. In field studies, only seroconversion has been demonstrated in pigs receiving two 1ml doses.

For vaccination with one dose of 2ml, protection has been shown 24 days after vaccination. 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 ADMINIS-TRATION

Dose:

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

Pigs from 21 days of age: single dose of 2ml or two doses of 1ml 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 (+2ºC to +8ºC)
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

31st March 2007

15. OTHER INFORMATION

Pack sizes:

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

Not all pack sizes may be marketed.