**Particulars to appear on the outer package (for 10 ml, 6 x 10 ml, 50 ml and 100 ml)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**Maprelin**
75 µg/ml solution for injection for pigs
Peforelin

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml solution for injection contains:
**Active substance:**
Peforelin 75.00 µg
**Excipients:**
Chlorocresol 1.00 mg

## 3. PHARMACEUTICAL FORM

Solution for injection.

## 4. PACKAGE SIZE

1 x 10 ml
6 x 10 ml
1 x 50 ml
1 x 100 ml

## 5. TARGET SPECIES

Pigs (sows and gilts)

## 6. INDICATIONS

For zootechnical use and intended for group or herd treatment.
- Induction of the oestrous cycle in sows after weaning
- Induction of oestrus in sexually mature gilts following therapy to inhibit the oestrus cycle with progestagens

## 7. METHOD AND ROUTE OF ADMINISTRATION

For intramuscular use. For single application. Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Pigs: Meat and offal: Zero days

## 9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

Expiry date: month/year
Once broached, use by:
Shelf-life after first opening the immediate packaging: 28 days

## 11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C - 8 °C).

Protect from light
Keep the vial in the outer carton.

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

Dispose of waste material in accordance with local requirements.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS REGARDING SUPPLY AND USE

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

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn, Germany

## 16. MARKETING AUTHORISATION NUMBER

## 17. MANUFACTURER'S BATCH NUMBER

Batch number:

**Particulars to appear on the immediate package (label for 10 ml-vials)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**Maprelin**
75 µg/ml solution for injection for pigs
Peforelin

**2. QUANTITY OF THE ACTIVE SUBSTANCE**

**3. CONTENTS BY VOLUME**

10 ml

**4. ROUTE(S) OF ADMINISTRATION**

For intramuscular use.

**5. WITHDRAWAL PERIOD**

Pigs: Meat and offal: Zero days

**6. BATCH NUMBER**

Batch number:

**7. EXPIRY DATE**

Expiry date: month/year
Once broached, use by:

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**Particulars to appear on the immediate package (label for 50 ml- and 100 ml-vials)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**Maprelin**
75 µg/ml solution for injection for pigs
Peforelin

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml solution for injection contains:
**Active substance:**
Peforelin 75.00 µg
**Excipients:**
Chlorocresol 1.00 mg

## 3. PHARMACEUTICAL FORM

## 4. PACKAGE SIZE

50 ml / 100 ml

## 5. TARGET SPECIES

## 6. INDICATIONS

For zootechnical use and intended for group or herd treatment.
- Induction of the oestrous cycle in sows after weaning
- Induction of oestrus in sexually mature gilts following therapy to inhibit the oestrus cycle with progestagens

## 7. METHOD AND ROUTE OF ADMINISTRATION

For intramuscular use. For single application. Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Pigs: Meat and offal: Zero days

## 9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

Expiry date: month/year
Once broached, use by:

## 11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C - 8 °C).
Protect from light.
Keep the vial in the outer carton.

## 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR

**WASTE MATERIALS, IF ANY**

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS REGARDING SUPPLY AND USE

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

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany

## 16. MARKETING AUTHORISATION NUMBER

## 17. MANUFACTURER'S BATCH NUMBER

Batch number:

Revised: March 2014
AN. 01333/2012

**PACKAGE LEAFLET FOR:**
Maprelin 75 µg/ml solution for injection for pigs

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

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn, Germany

## 2. Name of the Veterinary Medicinal Product

Maprelin 75 µg/ml solution for injection for pigs
Peforelin

## 3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Maprelin is a clear, colourless aqueous solution for injection containing:

*Active substance:*
Peforelin 75.0 µg/ml
Excipients:

Chlorocresol 1.0 mg/ml

## 4. Indications

For zootechnical use and intended for group or herd treatment.

- Induction of the oestrous cycle in sows after weaning
- Induction of oestrus in sexually mature gilts following therapy to inhibit the oestrus cycle with progestagens

## 5. Contraindications

Do not use in prepubertal gilts, in case of infertility or general health disorders.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

## 6. Adverse reactions

None observed.

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

## 7. Target species

Pigs (sows and gilts)

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

Dosage in µg Peforelin and ml product per animal. The dosage is dependent on the parity.

| | | |
|---|---|---|
| *Primiparous sows* | 24 hours after weaning off the piglets: | 37.5 µg = 0.5 ml |
| *Pluriparous sows* | 24 hours after weaning off the piglets: | 150 µg = 2.0 ml |
| *Gilts* | 48 hours after the termination of the medication for the inhibition of the cycle: | 150 µg = 2.0 ml |

For intramuscular injection. For single application.
Use automatic syringe equipment for the 50 ml and 100 ml vials.

## 9. ADVICE ON CORRECT ADMINISTRATION

None.

## 10. Withdrawal period

Pig:
Meat and offal zero days

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store in a refrigerator (2 °C - 8 °C).

Protect from light.

Keep the vial in the outer carton.
Do not use after the expiry date which is stated on the vial and carton.

Shelf life after first opening the container: 28 days.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided on the label.

## 12. SPECIAL WARNINGS

Special warnings for each target species:

None.

*Special precautions for use:*

Special precautions for use in animals:

None.

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

*The product might induce irritation and sensitization.*

People with known hypersensitivity to GnRH-analogues or any of the excipients should avoid contact with the veterinary medicinal product.
The veterinary medicinal product should not be administered by pregnant women, as an accidental self injection by the user cannot be excluded and because GnRH analogues have been shown to be foetotoxic in laboratory animals. Women of childbearing age should administer the product with special caution.
In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of accidental contact with the skin, the corresponding area should be thoroughly cleaned with soap and water, as GnRH analogues may be absorbed through the intact skin.
In case of contact with the eyes, they should be thoroughly rinsed with water.

*Use during pregnancy, lactation or lay:*

The safety of the product has not been established in sows and gilts during pregnancy and lactation. Laboratory studies in mice produced evidence of teratogenic effects. Do not use the product in animals during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

The simultaneous treatment of the product with PMSG or hCG can possibly lead to an over-reaction of the ovaries.

No interactions were reported following administration of the product 48 hours after the end of prior altrenogest therapy.

**Overdose (symptoms, emergency procedures, antidotes), if necessary:**

No adverse reactions were ascertained in pigs following treatment with up to three times the highest recommended dosage.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

**……**

## 15. OTHER INFORMATION

1 vial (10 ml) in a cardboard box
6 vials (10 ml) in a cardboard box
1 vial (50 ml) in a cardboard box
1 vial (100 ml) in a cardboard box

Not all pack sizes may be marketed.