PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maprelin 75 µg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Peforelin 75 µg

3. PACKAGE SIZE

10 ml
6 x 10 ml
50 ml
100 ml

4. TARGET SPECIES

Pigs (sows and gilts).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs:
Meat and offal: zero days

8. EXPIRY DATE

Exp.: {mm/yyyy}

Once broached use within 28 days.
Use by: …

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Veyx-Pharma GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 27569/4000

15. BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (Glass vial 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maprelin 75 µg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Peforelin 75 µg

3. TARGET SPECIES

Pigs (sows and gilts).

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Pigs:
Meat and offal: zero days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Use by: …

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Veyx-Pharma GmbH

9. BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS Glass vial (10 ml, 20 ml, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maprelin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Peforelin 75 µg

3. BATCH NUMBER

Lot: {number}

4. EXPIRY DATE

Exp.: {mm/yyyy}

Once broached use within 28 days.
Use by: …

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Maprelin 75 µg/ml solution for injection for pigs

2. Composition

Each ml contains:

Active substance:
Peforelin 75 µg

Excipients:
Chlorocresol 1.0 mg

Clear, colourless solution.

3. Target species

Pigs (sows and gilts).

4. Indications for use

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 cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product might induce irritation and sensitization.
People with known hypersensitivity to GnRH analogues, such as Peforelin, 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 veterinary medicinal 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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies in mice produced evidence of teratogenic effects. Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
The simultaneous treatment of the veterinary medicinal product with PMSG or hCG can possibly lead to an over-reaction of the ovaries.
No interactions were reported following administration of the veterinary medicinal product 48 hours after the end of prior altrenogest therapy.

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

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

7. Adverse events

None.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intramuscular use.
For single application.

Dosage in µg Peforelin and ml of the veterinary medicinal 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

Use automatic syringe equipment for the 50 ml and 100 ml vials.

9. Advice on correct administration

None.

10. Withdrawal periods

Pigs:
Meat and offal: zero days

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 27569/4000

Pack sizes:
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.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse events:
Veyx-Pharma GmbH
Soehreweg 6
Schwarzenborn
34639
Germany
Tel: +49 5686 9986 62
E-mail: pharmacovigilance@veyx.de

Manufacturer responsible for batch release:
Veyx Pharma BV
Forellenweg 16
NL-4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse events:
GB:
Anupco Ltd. T/A Kela Animal Health UK
Office 39, Lodge House, Lodge Park, Lodge Lane
Langham, Colchester
Essex, CO4 5NE
England
Tel.: +44 1206 233528
E-mail: sales@kela.health

NI:
Kela Veterinaria nv
Nieuwe Steenweg 62
9140 Elversele
Belgium
Tel.: +32 (0)3 780 63 90
E-mail: info.vet@kela.health

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

17. Other information

POM-V

Gavin Hall

Approved: 30 June 2026