Maprelin®

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Injection solution for pigs

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT
Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
Germany

NAME OF THE VETERINARY MEDICINAL PRODUCT
Maprelin® 75 µg/ml
Injection solution for pigs
Peforelin

STATEMENT OF THE ACTIVE SUBSTANCES 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

INDICATIONS
For biotechnical use, for medicated treatment of groups or herd application.

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

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.

ADVERSE REACTIONS
None known.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon or pharmacist.

TARGET SPECIES
Pigs (sows and gilts)

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Dosage in µg Peforelin and ml Maprelin® 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 administration.
Use automatic syringe equipment for the 10 ml and 50 ml vials.

ADVICE ON CORRECT ADMINISTRATION
None.

WITHDRAWAL PERIODS
Pigs: Meat and offal Zero days

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 shelflife 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.

SPECIAL WARNING(S)
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. Persons with a known hypersensitivity to GnRH analogues or any of the excipients should not administer the veterinary medicinal product. Pregnant women should not administer the veterinary medicinal product, 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 in childbearing age should administer the product with special caution.
In the case of accidental self-injection, seek medical advice and show the package leaflet to the doctor. 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 Maprelin® in animals during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
The simultaneous treatment of Maprelin® with PMSG or hCG can possibly lead to an overreaction of the ovaries.
No interactions were reported following administration of the product 48 hours after the end of a preceding 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.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required.

To be supplied only on veterinary prescription.

OTHER INFORMATION
Package sizes:
10 ml vial
50 ml vial

Not all package sizes may be marketed.