



DECAPEPTYL P.R. 11.25 mg
Triptorelin
powder and solvent for suspension for injection (I.M.),
3-month prolonged release form.

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What DECAPEPTYL P.R. 11.25 mg is and what it is used for ?
2. Before you use DECAPEPTYL P.R. 11.25 mg ?
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4. Possible side effects ?
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6. Further information.

1. WHAT DECAPEPTYL P.R. 11.25 mg IS AND WHAT IT IS USED FOR ?

This medicine is an analogue of a natural hormone.

It is used:

- in men: for certain prostate and bone diseases ;
- in women: for the treatment of endometriosis.

2. BEFORE YOU USE DECAPEPTYL P.R. 11.25 mg ?

Do not use DECAPEPTYL P.R. 11.25 mg if you are allergic to triptorelin or any of the excipients, or any medicine of the same group.

Take special care with DECAPEPTYL P.R. 11.25 mg :

Patients receiving this treatment should be kept under close medical supervision with sometimes regular, biological, clinical and radiological controls.

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Pregnancy

This medicine should not be used during pregnancy. If you discover that you are pregnant and are taking this medicine, please notify your doctor immediately and he/she will stop the treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW TO USE DECAPEPTYL P.R. 11.25 mg ?

Dosage

One injection every 3 months.

If you have the impression that the effect of DECAPEPTYL P.R. 11.25 mg is too strong or too weak, talk to your doctor or pharmacist.

Method of administration

Intramuscular route.

The powder should be reconstituted with the solution provided immediately before injection. The suspension obtained should not be mixed with other medicinal products.

N.B. : The injection should be prepared in strict compliance with the instructions given below. Any incomplete injections resulting in the loss of suspension volumes greater than the volume generally remaining in the injection syringe must be reported.

Duration of treatment

The treatment in women should be given for at least 3 months and for at most 6 months.

If you take more DECAPEPTYL P.R. 11.25 mg than you should:

Ask immediately you doctor or pharmacist.

If you forget to take DECAPEPTYL P.R. 11.25 mg :

Ask your doctor.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking DECAPEPTYL P.R. 11.25 mg :

In women, possibility of ovarian activity (ovulation, menses).

4. POSSIBLE SIDE EFFECTS ?

Like all medicines, DECAPEPTYL P.R. 11.25 mg can cause side effects, although not everybody gets them.

In men

In a few rare cases, the disorders for which you are receiving the treatment (urinary disorders, pain) may worsen at the beginning of the treatment. This may occur even if the treatment is producing a favourable effect.

You should nevertheless immediately notify your doctor of this phenomenon.

During treatment, the following may occur, even though the treatment is having a favourable effect: hot flushes, decreased libido and impotence, disappearing when the treatment is stopped.

In women

In a few rare cases, the disorders for which the treatment has been justified (pelvic pain, dysmenorrhoea) may be exacerbated at the beginning of the treatment, but should disappear in one to two weeks. This may occur even if the treatment is producing a favourable effect. You should nevertheless immediately notify your doctor of this phenomenon.

The following may occur during the treatment even though the medicine is having a favourable effect: hot flushes, vaginal dryness, headache, asthenia, decreased libido.

In both men and women

You may experience an allergic reaction or more rarely, nausea, vomiting, weight gain, hypertension, mood disorders, visual disturbances, fever or pain at the injection site.

Prolonged use of this medicine in adults may lead to a decrease of the bone mass. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DECAPEPTYL P.R. 11.25 mg ?

Keep out of the reach and sight of children.

Do not use DECAPEPTYL P.R. 11.25 mg after the expiry date which is stated on the box

Do not store above 25°C.

Inject immediately after reconstitution.

Do not use DECAPEPTYL P.R. 11.25 mg if you notice any visible signs of deterioration on packaging or blisters. Inform your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What DECAPEPTYL P.R. 11.25 mg contains ?

Triptorelin11.25 mg*
(as triptorelin pamoate)

per dosage unit

* Taking into account the characteristics of the pharmaceutical form, each vial contains a quantity of triptorelin pamoate corresponding to 15 mg of triptorelin

The other ingredients are:

D,L lactide-coglycolide polymer ; mannitol ; sodium carmellose ; polysorbate 80.

Solvent : mannitol ; water for injections.

What DECAPEPTYL P.R. 11.25 mg looks like and contents of the pack ?

This medicine is available as powder and solvent for suspension for injection (IM), prolonged release form. Box of 1 vial of powder and 1 vial of solvent.

Marketing Authorisation Holder / Distributor

IPSEN PHARMA
65, quai Georges Gorse
92100 Boulogne-Billancourt

Manufacturer

IPSEN PHARMA BIOTECH
Parc d'activités du plateau de Signes
83870 Signes

This leaflet was last approved in 09/2009.

Detailed information on this medicine is available on the Afsaps website (France).

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To be read carefully before the injection.

INSTRUCTIONS FOR USE

1

PREPARATION OF THE PATIENT

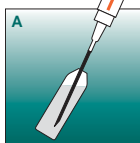
- The patient should be in a prone position, buttock skin disinfected.

2

PREPARATION OF THE INJECTION

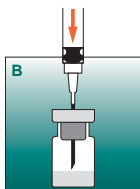
The presence of bubbles on top of the lyophilisate is a normal appearance of the product.

- Break the neck of the vial (dot face up).



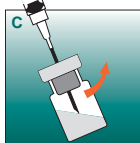
- Draw up all the solvent into the syringe with the needle.

- Remove the green tab on top of the vial.



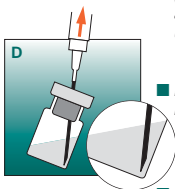
- Transfer the solvent into the vial containing the powder.

- Pull up the needle above the liquid level. Do not remove the needle from the vial.



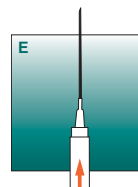
- Shake without inverting the vial until an homogeneous mixture is obtained.

- Check the absence of agglomerates before drawing up the suspension (in the event of presence of agglomerates, carry on the shaking until complete homogenization).



- Draw up all the suspension without inverting the vial.

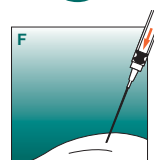
- Remove the needle used for the reconstitution and attach the other needle on the syringe tip (screw on tight). Only grasp the colored hub to connect needle.



- Push the air from the syringe.

3

INTRAMUSCULAR INJECTION



- Inject immediately in the gluteal muscle with the needle.

4

AFTER USE

- Dispose the needles in a designated sharp container.