PACKAGE LEAFLET: INFORMATION FOR THE USER

DECAPEPTYL P.R. 3 mg

powder and solvent for suspension for injection (I.M.),
28-day prolonged release form.
Triptorelin

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. 3 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 children: for the treatment of precocious puberty,
in women
for the treatment of endometriosis,
for the treatment of certain female infertilities. This medicine is generally combined with other hormones (called gonadotrophins) when used for in vitro fertilisation procedures (I.V.F.E.T).
in the treatment of certain uterine fibromyomas prior to surgery.

2. WHAT DO YOU NEED TO KNOW BEFORE YOU USE DECAPEPTYL P.R. 3 MG ?

Do not use DECAPEPTYL P.R. 3 mg
if you are allergic (hypersensitive) to triptorelin, gonadotropin releasing hormone (GnRH), other GnRH analogues or any of the excipients of DECAPEPTYL PR 3 mg.
if you are pregnant or breast-feeding.

Take special care with DECAPEPTYL P.R. 3 mg :
Patients receiving this treatment should be kept under close medical supervision with sometimes regular, biological, clinical and radiological controls.
If you are using medicines for preventing your blood clotting (anticoagulant), since you may experience bruising at the site of injection.
There have been reports of depression in patients taking DECAPEPTYL PR 3 mg which may be severe. If you are taking DECAPEPTYL PR 3 mg and develop depressed mood, inform your doctor.
DECAPEPTYL PR 3 mg can induce mood changes.
Treatment with DECAPEPTYL PR 3 mg or other GnRH analogues may increase the risk of developing thin or weak bones, especially if you are a heavy drinker, a smoker, have a family history of osteoporosis (a condition that affects the strength of your bones), have a poor diet or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids). If you have anything wrong with you that affects your bones, such as osteoporosis, tell your doctor. This may affect the way your doctor decides to treat you.
If you have diabetes or if you suffer from heart problems, inform your doctor.
If you have an enlargement (benign tumour) of the pituitary gland that you were unaware of, this may be discovered during treatment with DECAPEPTYL PR 3 mg. Symptoms include sudden headache, vomiting, problems with eye sight and paralysis of the eyes.
In men
At the beginning of treatment there will be an increased amount of testosterone in your body. This may cause the symptoms of the cancer to get worse. Contact your doctor if this happens. The doctor may give you some medicine (an anti-androgen) to prevent your symptoms from getting worse.
During the first weeks of treatment, DECAPEPTYL PR 3 mg may, as with other GnRH analogues, in isolated cases, cause the spinal cord to compress or the urethra (where you pass urine) to block. You will be monitored by your doctor and given treatment for these conditions if they occur.
After surgical castration triptorelin does not induce any further decrease in serum testosterone levels and therefore should not be used after orchidectomy.
Diagnostic tests of pituitary gonadal function conducted during treatment or after discontinuation of therapy with DECAPEPTYL P.R. 3 mg may be misleading.
In women
During infertility treatment, the gonadotrophins combined with the product may induce an increase of the size of the ovaries or an ovarian hyperstimulation which can induce a pelvic and/or abdominal pain and difficulties to breath. If this occurs, consult your doctor immediately.
You may have some vaginal bleeding in the first month of treatment. After that your periods normally stop. Tell your doctor if you have bleeding after the first month of treatment.
Your periods should start about 2 to 3 months after the last injection.
When the treatment is not for infertility, you must use some form of contraception other than the 'pill' during all the treatment and till the menses are back (see section pregnancy and breast-feeding).
In children
Girls who have an early puberty may have some vaginal bleeding in the first month of treatment.
A pathology of the hip may occur after stopping treatment (slipped capital femoral epiphysis of the hip). It results in stiffness of the hip, a limp and / or severe pain in the groin radiating to the thigh. If this occurs, you should consult your doctor.
If you or your children are concerned by any sign listed above, talk to your doctor.

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If you or your children are concerned by any sign listed above, talk to your doctor.

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
DECAPEPTYL PR 3 mg should not be used during pregnancy or breast-feeding.
Do not use DECAPEPTYL PR 3 mg if you are trying to get pregnant (unless if DECAPEPTYL is being used as part of a treatment for infertility).
Ask your doctor or pharmacist for advice before taking any medicine.
Driving and using machines
You may feel dizzy, tired or have problems with your sight such as blurred vision. These are possible side effects of treatment or from the underlying disease. If you experience any of these side effects, you should not drive or use machines.
Important information about some components of DECAPEPTYL PR 3 mg
This medication contains sodium. The rate of sodium is less than 1 mmol (23 mg) per dose, that is to say without sodium.

3. HOW TO USE DECAPEPTYL P.R. 3 MG ?

Posology
One injection every 4 weeks.
In children:
The dose is adjusted according to body weight.
Children under 20 kg in body weight: half a dose by intramuscular route, every 4 weeks (28 days), i.e. administer half the volume of the reconstituted suspension.
Children between 20 and 30 kg in body weight: two-thirds of the dose by intramuscular route, every 4 weeks (28 days), i.e. administer two-thirds of the volume of the reconstituted suspension.
Children over 30 kg in body weight: one intramuscular injection every 4 weeks (28 days).
If you have the impression that the effect of DECAPEPTYL P.R. 3 mg is too strong or too weak, talk to your doctor or pharmacist.

Method and route 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 duration of treatment will be adapted to the individual case.
Follow your doctor's prescription.
If you take more DECAPEPTYL P.R. 3 mg, than you should :
Ask immediately you doctor or pharmacist.
If you forget to take DECAPEPTYL P.R. 3 mg :
Ask you doctor.
Do not take a double dose to make up for forgotten individual doses
Effects when treatment with DECAPEPTYL P.R. 3 mg, is stopped
In women, recovery of ovarian activity (ovulation possibility, menses).

4. POSSIBLE SIDE EFFECTS

Like all medicines, DECAPEPTYL P.R. 3 mg can cause side effects, although not everybody gets them.
In rare cases you may experience a severe allergic reaction. Tell your doctor immediately if you develop symptoms such as swallowing or breathing problems, swelling of your lips, face, throat or tongue, a rash.
Prolonged use of this medicine in adults may lead to a decrease of the bone mass.
If you have an enlargement (benign tumour) of the pituitary gland that you were unaware of, this may be discovered during treatment with DECAPEPTYL PR 3 mg. Symptoms include sudden headache, vomiting, problems with eye sight and paralysis of the eyes.
An increase in white blood cell count may be found, as with other GnRH analogues, in patients being treated with DECAPEPTYL PR 3 mg.
In men
Most side effects are expected, due to the change in testosterone in the body. These effects include hot flashes, impotence and decreased libido.
Very common side effects affecting more than 1 in 10 patients:
Hot flushes
Weakness (asthenia)
Excessive sweating
Back pain
Pins and needles sensation in the legs

Common side effects affecting 1 to 10 patients of 100
Depression, mood changes
Nausea
Tiredness, reaction at the injection site (redness, bruising and/or pain), muscle and bone pain, pain in the arms and legs, oedema (build up of fluid in the body tissues)
Dizziness, headache
Impotence, loss of libido

Uncommon side effects affecting 1 to 10 patients of 1000 patients:
Ringing in the ears
Pain in abdomen, constipation, diarrhoea, vomiting
Drowsiness, shaking, sleepiness, pain
Some blood tests affected (including raised liver function tests)
Increase in weight
Loss of appetite, gout (severe pain and swelling in the joints usually in the big toe),
Increase in appetite
Joint pain, muscle cramp, muscle weakness, muscle pain
Tingling or numbness
Inability to sleep, irritability
Development of enlarged breasts in men, breast pain, reduction in testicular size, pain in testicles
Difficulty in breathing
Acne, hair loss, itching, rash
High blood pressure

Rare side effects affecting 1 to 10 patients of 10,000 patients:
Red or purple discolorations on the skin
Diabetes
Vertigo
Abnormal sensation in the eye, blurring or disturbance in vision
Sensation of fullness in the abdomen, flatulance, dry mouth, abnormal sense of taste
Chest pain
Difficuty in standing
Flu-like symptoms, fever
Allergic reaction, anaphylactic reaction (serious allergic reaction which can cause dizziness or difficulty in breathing)
Inflammation of the nose/throat (rhinopharyngitis)
Increased body temperature
Weight loss
Stiff joints, joint swelling, musculoskeletal stiffness, osteoarthiritis
Memory loss
Feeling confused, decreased activity, having a feeling of elation or well-being
Ejaculation trouble
Shortness of breathe when lying flat
Blisters
Nosebleed
Low blood pressure

Frequency not known (cannot be estimated from the available data)
Blurred vision
General discomfort with quick swelling of the face and neck related to allergic reaction (angioedema)
Urticaria
Blood pressure increased
Anxiety
Bone pain
Discomfort

An increase in white blood cell count may be found, as with other GnRH analogues, in patients being treated with DECAPEPTYL PR 3 mg.
Patients receiving long-term treatment by GnRH analogue in combination with radiation may have more side effects especially gastrointestinal, related to radiotherapy.
In women
Many of the side effects are expected due to the change in the level of oestrogens in your body. These very common effects **(affect more than 1 patient in 10)** include headache, decreased libido, mood changes, difficulty in sleeping, pain during or after sexual intercourse, painful periods, genital bleeding, pelvic pain, dryness of the vagina, excessive sweating and hot flushes.
Other common side effects **(affect 1 to 10 patients of 100)** may occur including depression (long term treatment) breast pain, muscle cramps, painful joints, weight gain, nausea, abdominal pain or discomfort, redness, inflammation and/or pain at the injection site.
Other common side effects **(affect 1 to 10 patients of 1000)** may occur including depression (short term treatment).
Other reported side effects are **(their frequency cannot be estimated from the available data)**: vomiting, diarrhea, fever, general discomfort, increased blood pressure, muscle pain and weakness, confusion, anxiety, dizziness, absence of periods, allergic reactions, angioedema (swelling of the lips, face, throat and/or tongue), skin rash, itching, urticaria, difficulty in breathing, vertigo, abnormal sensations in the eyes and/or changes in sight.
During infertility treatment, the association with gonadotrophins may induce an increase of the size of ovaries or an ovarian hyperstimulation which can induce pelvic and/or abdominal pain or shortness of breath. If this occurs, consult your doctor as soon as possible.
In endometriosis treatment, 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.
In children
Common side effects **(affect 1 to 10 patients of 100)**: vaginal bleeding may occur in girls in the first month of treatment. Additional common adverse reactions may be observed such as a depression, mood changes, injection site reactions (redness, inflammation and/or pain), headache, hot flushes and/or hypersensitivity reactions.
The following reactions have also been reported **(their frequency cannot be estimated from the available data)**: weight gain, increased blood pressure, blurred or abnormal vision, abdominal pain and/or discomfort, vomiting, nose bleeding, feeling unwell, muscle pain, mood disorders, nervousness, and angioedema (swelling of the lips, face, throat and/or tong) skin rash, urticaria.
Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: Agence nationale de sécurité du médicament et des produits de santé (Ansm) and network of the Centres Régionaux de Pharmacovigilance – Internet site: www.ansm.sante.fr. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DECAPEPTYL P.R. 3 MG ?

Keep out of the reach and sight of children.
After opening: the product must be used immediately.
Do not use after the expiry date stated on the packaging.
Do not store DECAPEPTYL PR 3 mg above 25 °C.
Inject immediately after reconstitution.
Do not use DECAPEPTYL P.R. 3 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. 3 mg contains ?
The active substance is :

Triptorelin ..... 3 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 4.3 mg of triptorelin.

The other ingredients are:
Poly (d,l-lactide-co-glycolide), mannitol, carmellose sodium, polysorbate 80.
Solvent: mannitol, water for injections.
What DECAPEPTYL P.R. 3.mg looks like and contents of the pack ?
This medicinal product is a powder and solvent for prolonged-release suspension for injection (IM). Pack of 1 vial and 1 ampoule.
Marketing Authorisation Holder
IPSEN PHARMA
65 QUAI GEORGES GORSE
92100 BOULOGNE-BILLANCOURT
Distributor
IPSEN PHARMA
65 QUAI GEORGES GORSE
92100 BOULOGNE-BILLANCOURT
Manufacturer
IPSEN PHARMA BIOTECH
PARC D'ACTIVITE DU PLATEAU DE SIGNES
83870 SIGNES
Not applicable.
The leaflet was last approved on 16 July 2015
Detailed information on this medicine is available on the web site of ANSM (France).

IPSEN CE 0459

FOLLOWING INFORMATION IS ONLY FOR HEALTHCARE PROFESSIONALS (SEE SECTION 3):

INSTRUCTIONS FOR USE
Prepare the patient by disinfecting the injection site. This operation needs to be performed first because once reconstituted, the drug should be injected immediately.

2. PREPARATION OF THE INJECTION

Two needles are provided in the box :
- **Needle 1** : a long needle (38mm) without safety device to be used for reconstitution
- **Needle 2** : a long needle (38mm) with safety device to be used for injection

Needle 1 – 38 mm

20 Gauge

Needle 2– 38 mm

20 Gauge

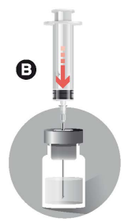
The presence of bubbles on top of the lyophilisate is a normal appearance of the product.

A

2a

- Take out the ampoule containing the solvent. Tap any solution within the tip of the ampoule back to the main body of the ampoule.
- Screw Needle 1 (without safety device) on to the syringe. Do not remove the needle protection yet.
- Break open the ampoule with dot face up.
- Remove the needle protection from Needle 1. Insert the needle in the ampoule and draw up all the solvent into the syringe.
- Put aside the syringe containing the solvent.

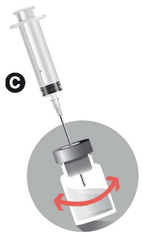
B



2b

- Take out the vial containing the powder; Tap any powder which has accumulated at the top of the vial back to the bottom of the vial.
- Remove the plastic tap on the top of vial.
- Take back the syringe containing the solvent and insert the needle through the ubber stopper vertically into the vial. Inject the solvent slowly, so that, if possible, it washes down the entire upper part of the vial

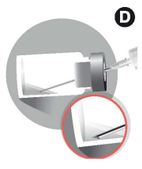
C



2c

- Pull up Needle 1 above the liquid level. Do not remove the needle from the vial. Reconstitute the suspension by swirling gently from side to side. Do not invert the vial.
- Make sure that the agitation is long enough to obtain an homogeneous and milky suspension.
- **Important : Check there is no unsuspended powder in the vial (if any powder clumps are present, continue swirling until they disappear)**

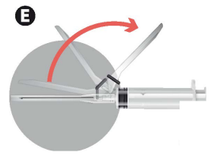
D



2d

- When the suspension is homogeneous, pull down the needle without inverting the vial, draw up all of the suspension. A small amount will remain in the vial and should be discarded. An overfill is included to allow for this loss.
  Grasp the coloured hub to disconnect the needle. Remove Needle 1 used for the reconstitution from the syringe. Screw on to the syringe Needle 2.
- Move the safety sheath away from the needle and towards the syringe barrel. The safety sheath remains in the position you set.

E

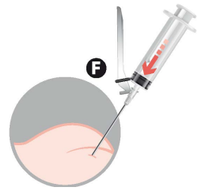


- Remove the needle protection from the needle.
- Prime the needle to remove air from the syringe and inject immediately.

3. INTRAMUSCULAR INJECTION

- To avoid precipitation, inject immediately subcutaneously or intramuscularly.

F

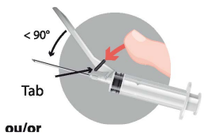


4. AFTER USE

- Note : Keep your finger behind the tab at all times

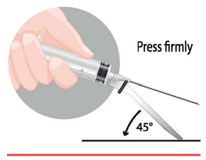
There are two alternatives to activate the safety system.

- Method A : push the tab forward with your finger

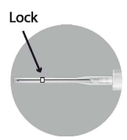


ou/or

- Method B : push the sheath to a flat surface



- In both cases press down with a firm quick motion until a distinct audible click is heard.
- Visually confirm that the needle is fully engaged under the lock.



Used needles, any unused suspension or other waste material should be disposed of in accordance with local requirements.