

Décapeptyl 0,1_{mg}

triptorelin

PACKAGE LEAFLET: INFORMATION FOR THE USER

DECAPEPTYL 0.1 mg, powder and solvent for solution for injection (S.C.). 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any 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 0.1 mg is and what it is used for?
2. What do you need to know before you use DECAPEPTYL 0.1 mg ?
3. How to use DECAPEPTYL 0.1 mg ?
4. Possible side effects
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6. Further information

1. WHAT DECAPEPTYL 0.1 mg, IS AND WHAT IT IS USED FOR ?

GONADOTROPHIN-RELEASING HORMONE ANALOGUE

(L 02 AE04: antineoplastic and immunomodulator).

This medicine is an analogue of a natural hormone.

It is used:

- in men for certain diseases of the prostate and bone,
- in women for the treatment of certain female infertilities. This medicine is generally combined with other hormones (called gonadotrophins) when used for *in vitro* fertilisation (I.V.F.E.T).

2. WHAT DO YOU NEED TO KNOW BEFORE YOU USE DECAPEPTYL 0.1 mg ?

Do not use DECAPEPTYL 0.1 mg

- if you are allergic (hypersensitive) to triptorelin, gonadotropin releasing hormone (GnRH), other GnRH analogues or any of the excipients of DECAPEPTYL 0.1 mg.
 - if you are pregnant or breast-feeding.
- If you have any doubt, it is essential to ask your doctor or pharmacist for advice.

Take special care with DECAPEPTYL 0.1 mg

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 0.1 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 0.1 mg may be misleading.

Long treatment with DECAPEPTYL 0.1 mg or other GnRH analogues may lead to bone loss, osteoporosis (a condition that affects the strenght of your bones) and may increase the risk of bone fracture, especially if you are a heavy drinker, a smoker, have a family history of osteoporosis, have a poor diet or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids).

If you have diabetes or if you suffer from heart problems or depression, 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 0.1 mg. Symptoms include sudden headache, vomiting, problems with eye sight and paralysis of the eyes.

In women

Long treatment with DECAPEPTYL 0.1 mg or other GnRH analogues may lead to bone loss, osteoporosis (a condition that affects the strenght of your bones) and may increase the risk of bone fracture, especially if you are a heavy drinker, a smoker, have a family history of osteoporosis, have a poor diet or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids).

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 breathe. If this occurs, consult your doctor immediately.

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

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

If you have any doubt, it is essential to ask your doctor or pharmacist for advice.

Using other medicines

In order to avoid interactions between several medicinal products, you should inform your doctor or pharmacist if you are taking any other treatment.

Pregnancy and breast-feeding

DECAPEPTYL 0.1 mg should not be used during pregnancy or breast-feeding.

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.

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 DECAPEPTYL 0.1 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 0.1 mg ?

Posology

One injection a day.

Duration of treatment will be adapted to the individual case.

In all cases please follow exactly your doctor's prescription. Do not stop the treatment without first consulting your doctor.

Method of administration

Subcutaneous route.

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

Frequency of administration

Your treatment must be taken regularly as indicated by your doctor's prescription.

Duration of treatment

Comply strictly with your doctor's prescription.

If you take more DECAPEPTYL 0.1 mg, than you should :

Ask immediately you doctor or pharmacist.

If you forget to take DECAPEPTYL 0.1 mg:

In any case, ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DECAPEPTYL 0.1 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 start of the treatment. This may occur even if the treatment is producing a favourable effect and usually disappear after one to two weeks.

You should nevertheless immediately notify your doctor of this phenomenon.

Most side effects are expected, due to the change in testosterone in the body. These effects include hot flashes, impotence and decreased libido (affecting 1 to 10 patients of 100).

An increase in white blood cell count may be found, as with other GnRH analogues, in patients being treated with DECAPEPTYL 0.1 mg.

In women

During infertility treatment, the association with gonadotrophins may induce 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.

At the beginning of treatment with triptorelin 1-month and 3-month formulations: genital bleeding during the first month of treatment

During treatment with triptorelin 1-month and 3-month formulations: sleep disorder, headache, mood altered, vulvovaginal dryness and itching, pain during sex relations, libido decreased.

During treatment with triptorelin 1-month formulation: breast pain, muscle spasms, joint pain, weight increased, nausea, abdominal pain/discomfort, tiredness.

The following adverse reactions have also been reported (frequency unknown): headaches, blurred vision episode or visual disturbances.

In all

Hot flushes and excessive sweating are very common (affect more than 1 in 10).

Allergic reactions are possible, and more rarely nausea, vomiting, weight gain, hypertension, mood disorders, visual disturbances, fever and pain at the injection site.

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 0.1 mg. Symptoms include sudden headache, vomiting, problems with eye sight and paralysis of the eyes.

If you notice any side effects not listed in this leaflet, or if the side effects get serious, please tell your doctor or pharmacist.

5. HOW TO STORE DECAPEPTYL 0.1 mg ?

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the packaging.

This medicinal product does not require any special storage precautions.

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 0.1 mg contains ?

The active substance is :

Triptorelin 0.1 mg
Per one dose

The other ingredients are:

Mannitol

Solvent: sodium chloride, water for injections.

What DECAPEPTYL 0.1 mg looks like and contents of the pack ?

This medicinal product is a powder and solvent for solution for injection (SC). Pack of 7 vials and 7 ampoules.

Marketing Authorisation Holder/Distributor

IPSEN PHARMA

65 QUAI GEORGES GORSE

92100 BOULOGNE-BILLANCOURT

Manufacturer

IPSEN PHARMA BIOTECH

PARC D'ACTIVITE DU PLATEAU DE SIGNES

83870 SIGNES

The leaflet was last approved on 19th June 2012.

Detailed information on this medicine is available on the web site of ANSM (France).



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