Package leaflet: Information for the user

Decapeptyl® 6-month 22.5mg powder and solvent for prolonged-release suspension for injection
(triptorelin)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you use Decapeptyl 6-month
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1. What Decapeptyl 6-month is and what it is used for

Decapeptyl 6-month contains triptorelin, which is similar to a hormone called gonadotropin releasing hormone (GnRH analogue).

Triptorelin belongs to a group of medicines called GnRH analogues. It is a long acting formulation designed to slowly deliver 22.5 mg of triptorelin over a 6-month period (twenty four weeks). In men, triptorelin lowers the levels of the hormone testosterone. In women, it lowers the levels of the hormone oestrogen.

In men: Decapeptyl 6-month is used to treat both locally advanced prostate cancer (limited in the prostate gland itself) and prostate cancer which has spread to other parts of the body (metastatic cancer).

In children 2 years of age and older: Decapeptyl 6-month is used to treat puberty that occurs at a very young age, i.e. before 8 years of age in girls and 10 years of age in boys (central precocious puberty). This is called 'early puberty' in the rest of this leaflet.

2. What you need to know before you use Decapeptyl 6-month

Do not use Decapeptyl 6-month
- If you are **allergic** (hypersensitive) to triptorelin pamoate, gonadotropin releasing hormone (GnRH), other GnRH analogues or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or breast-feeding.

Warnings and precautions
- Talk to your doctor or pharmacist before taking Decapeptyl 6-month. There have been reports of depression in patients taking Decapeptyl 6-month which may be severe. If you are taking Decapeptyl 6-month and develop depressed mood, **inform your doctor**. Your doctor may want to monitor your depression during your treatment.
- If you are using medicines for preventing your blood clotting, since you may experience bruising at the site of injection.
- If any convulsion occur, inform immediately your doctor. There have been reports of convulsions in patients receiving triptorelin or similar medicines. These occurred in patients with or without medicinal history of epilepsy.

The product should only be injected in the muscle.

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 worsen. **Contact your doctor** if this happens. The doctor may give you some medicine (an anti-androgen) to prevent your symptoms from getting worse.
- You may experience symptoms due to compression of your spinal cord (e.g. pain, numbness or weakness of legs) or a blockage in the urethra (where you pass urine) during the first weeks of treatment. If any of these symptoms occur, contact your doctor immediately, who will assess and treat you for these conditions appropriately.
- You should not receive Decapeptyl 6-month if you have had an operation to remove your testicles. Triptorelin does not include any further decrease in serum testosterone levels.
- In adults, Decapeptyl 6-month may cause thinning of the bones (osteoporosis) with an increased risk of bone fractures. You should tell your doctor if you have any of the below risk factors as he/she might prescribe you another medicine (called a bisphosphonate) to reduce bone loss. Risk factors may include:
  - If you or any of your close family have thinning of the bones.
  - If you drink excessive amounts of alcohol, and/or smoke heavily.
  - If you take medicines over a long period of time that may cause thinning of the bones, for example medicines for epilepsy or steroids (such as hydrocortisone or prednisolone).
- If you need any diagnostic tests to check your hormone function during or after your Decapeptyl 6-month treatment, the results may be misleading. Please tell your doctor you have been treated with Decapeptyl 6-month.
- This type of hormone therapy that you are receiving has been associated with metabolic changes such as glucose intolerance and an increased risk of cardiovascular disease.
- **Tell your doctor** if you have diabetes.
- **Tell your doctor** if you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Decapeptyl 6-month.
- If you have an enlargement (benign tumour) of the pituitary gland that you were unaware of, this may be discovered during treatment with Decapeptyl 6-month. Symptoms include sudden headache, vomiting, problems with eye sight and paralysis of the eye muscles.
- As Decapeptyl 6-month reduces testosterone, it may cause changes in heart rhythm (QT prolongation). These changes are visible when you have an ECG.
- Treatment with GnRH analogues including Decapeptyl 6-month might increase the risk of anaemia (defined as a decrease in the count of red blood cells).

In children:
- If you have a progressive brain tumour, **tell your doctor.** This may affect the way your doctor decides to treat you.
- Girls who have an early puberty may have some vaginal bleeding in the first month of treatment.
- If your child suffers from a bad or recurrent headache, problems with eyesight and ringing or buzzing in the ears, contact a doctor immediately (see section 4).
- When treatment is stopped signs of puberty will occur. In girls, menstrual bleeding will start on average one year after stopping treatment.
  Early puberty caused by other diseases should be ruled out by your doctor.
  The amount of minerals in the bones decreases during the treatment but it returns to normal after treatment is stopped.
- Damage to 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.

Please talk with your doctor if you are concerned about any of the above.

Other medicines and Decapeptyl 6-month
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Decapeptyl 6-month might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, or think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not take Decapeptyl 6-month if you are pregnant.

Do not take Decapeptyl 6-month if you are breast-feeding.

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 of the ingredients of Decapeptyl 6-month
Decapeptyl 6-month is essentially 'sodium free' since it contains less than 1 mmol sodium (23mg) per dose and may be taken if you are on a low sodium diet.

3. How to use Decapeptyl 6-month

Decapeptyl 6-month will be administered to you under the supervision of a physician.

In men:
Therapy of prostrate cancer with Decapeptyl 6-month requires long term treatment.

The usual dose is 1 vial of Decapeptyl 6-month injected into a muscle every 6 months (24 weeks**)**.
Decapeptyl 6-month is for injection into the muscle only.
Decapeptyl 6-month will be given to you regularly to reduce testosterone levels. Your doctor will determine the treatment duration.

Blood tests may be performed by your doctor to measure how effective the treatment is.

In children:
You will usually receive an injection into a muscle every 6 months (24 weeks). Decapeptyl 6-month is for injection into the muscle only.
Your doctor will decide when treatment should be stopped (normally when you are about 12-13 years old if you are a girl and about 13-14 years old if you are a boy).
If you think the effect of Decapeptyl 6-month is too strong or too weak, contact your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine may 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.

In men:
As seen following treatment with other GnRH agonist therapies or after surgical castration, the most commonly observed adverse events related to triptorelin treatment were due to its expected pharmacological effects. These effects included hot flushes and decreased libido.

Increased lymphocyte count has been reported with patients undergoing GnRH analogue treatment.

With the exception of immuno-allergic reactions and injection site reactions, all adverse events are known to be related to changed testosterone levels.
As with other GnRH agonist, hypersensitivity and allergic (anaphylactic) reactions have been reported with triptorelin.

In other triptorelin products, uncommonly pressure sensitive infiltration at the injection site have been reported after subcutaneous injection.

Side effects which are **very common** (may affect more than 1 in 10 people) are:
- Hot flushes
- Weakness
- Excessive sweating
- Back pain
- Pins and needles sensation in the legs
- Reduced libido
- Impotence.

Side effects which are **common** (may affect up to 1 in 10 people) are:
- Nausea, dry mouth
- Pain, bruising, redness, and swelling at injection site
- Muscle and bone pain, pain in the arms and legs, oedema (build-up of fluid in the body tissues), lower abdominal pain
- High blood pressure
- Allergic reaction
- Increase in weight
- Dizziness, headache
- Loss of libido, depression, mood changes.

Side effects which are **uncommon** (may affect up to 1 in 100 people) are:
- Increase of blood platelets
- Feeling your heartbeat
- Ringing in the ears, vertigo, blurred vision
- Pain in abdomen, constipation, diarrhoea, vomiting
- Drowsiness, severe shivering associated with sweating and a fever, sleepiness, pain
- Some blood tests affected (including raised liver function tests)
- Blood pressure increased
- Weight loss
- Loss or increase of appetite, gout (severe pain and swelling in the joints usually in the big toe)
- Diabetes, excessive lipids in the blood
- Joint pain, muscle cramp, muscle weakness, muscle pain, swelling and tenderness, bone 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, redness of the skin, hives
- Waking up at night to pass urine, problems passing urine
- Nosebleeds.

Side effects which are **rare** (may affect up to 1 in 1000 people) are:
- Red or purple discolorations on the skin
- Abnormal sensation in the eye, blurring or disturbance in vision
- Sensation of fullness in the abdomen, flatulence, abnormal sense of taste
- Chest pain
- Difficulty in standing
- Flu-like symptoms, fever
- Anaphylactic reaction (serious allergic reaction which can cause dizziness or difficulty in breathing, swelling of the face or throat)
- Inflammation of the nose/throat
- Increased body temperature
- Stiff joints, joint swelling, musculoskeletal stiffness, osteoarthritis
- Memory loss
- Feeling confused, decreased activity, having a feeling of elation
- Shortness of breath when lying flat
- Blisters
- Low blood pressure.

Not known: Frequency cannot be estimated from the available data
- Anaphylactic reaction (serious allergic reaction which causes difficulty in breathing or dizziness, swelling of the face or throat)
- Changes in ECG (QT prolongation)
- General discomfort
- Anxiety
- Rapid formation of wheals due to swelling of the skin or mucous membranes
- Urinary incontinence
- If an existing pituitary tumour, an increased risk of bleeding to the area
- Anaemia (decrease in the count of red blood cells).

In children:
Side effects which are **very common** (may affect more than 1 in 10 people) are:
- Vaginal bleeding which may occur in girls in the first month of treatment.

Side effects which are **common** (may affect up to 1 in 10 people) are:
- Acne
- Headache
- Hot flushes
- Weight gain
- Pain in the abdomen
- Hypersensitivity reactions
- Pain, redness and swelling at injection site.

Side effects that are **uncommon** (may affect up to 1 in 100 people) are:
- Itching
- Neck pain
- Nosebleeds
- Constipation
- Blurred vision
- Rash or hives
- Nausea, vomiting
- Overweight
- Pain in the breast
- Changes in mood
- General discomfort.

Not known: Frequency cannot be estimated from the available data
- High blood pressure
- Abnormal vision
- Severe allergic reaction which causes difficulty swallowing, breathing problems, swelling of your lips, face, throat or tongue, or hives
- Convulsions
- Some blood tests affected including hormone levels
- Rapid formation of wheals due to swelling of the skin or mucous membranes
- Muscle pain
- Mood disorders
- Depression
- Nervousness.
- Idiopathic intracranial hypertension (increased intracranial pressure around the brain characterised by headache, double vision and other visual symptoms, and ringing or buzzing in the ears)

Your doctor will determine the countermeasures be to taken.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance: Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Decapeptyl 6-month

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and on the labels after EXP. The expiry date refers to the last day of that month.

Once opened/reconstituted, immediate use is recommended.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Decapeptyl 6-month contains
The active substance of Decapeptyl 6-month is triptorelin.
Each vial contains the quantity of triptorelin (as triptorelin pamoate) to ensure that the minimum triptorelin quantity injected is 22.5 mg.
The other ingredients are poly (D,L-lactide-co-glycolide), mannitol, carmellose sodium, polysorbate 80.
The solvent contains water for injections.

What Decapeptyl 6-month looks like and the contents of the pack
Decapeptyl 6-month is supplied as an off-white powder in a clear glass vial. Each vial contains enough product for one injection. The solvent contains 2mL of a clear, colourless liquid in a glass ampoule. Once reconstituted, around 2mL of milky liquid is formed.

After dispersion in 2mL solvent, 1mL of the reconstituted suspension contains 11.25mg triptorelin.
Decapeptyl 6-month is available in boxes of:
1 vial, 1 ampoule and 1 blister containing 1 injection syringe and 2 injection needles.

Manufacturer
Manufactured by:
IPSEN PHARMA BIOTECH, Parc d'Activites du Plateau de Signes, Chemin departemental 402, 83870 Signes, Frankreich.

Procured from within the EU and repackaged by:
BModesto B.V., Charles Lindberghlaan 8, 8218 NS Lelystad, Netherlands.

PPA holder: BModesto B.V., Minervaweg 2, 8239 DL, Lelystad, Netherlands.

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