PACKAGE LEAFLET: INFORMATION FOR THE USER

Pamorelin LA 3.75 mg powder and solvent for prolonged-release suspension for injection
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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT PAMORELIN® LA 3.75 MG IS AND WHAT IT IS USED FOR

Pamorelin® LA 3.75 mg contains triptorelin, which is similar to a hormone called gonadotropin releasing hormone (GnRH analogue). It is a long acting formulation designed to slowly deliver 3.75 mg of triptorelin over a 1-month period (four weeks). It acts by lowering the levels of the male hormone, testosterone, in the body.

Pamorelin® LA 3.75 mg is used to treat locally advanced, hormone-dependent_prostate cancer alone or during and following radiation therapy. It is also used to treat hormone-dependent prostate cancer which has spread to other parts of the body (metastatic cancer).

2. BEFORE YOU USE PAMORELIN® LA 3.75 mg

Do not use Pamorelin® LA 3.75 mg

if you are allergic (hypersensitive) to triptorelin embonate, gonadotropin releasing-hormone (GnRH), other GnRH analogues or any of the excipients of Pamorelin® LA 3.75 mg.

Take special care with Pamorelin® LA 3.75 mg

- With intramuscular injection,if you are using medicines for preventing your blood clotting, since you may experience bruising at the site of injection.
- At the beginning of the 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, Pamorelin 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 Pamorelin® LA 3.75 mg may be misleading.
- Tretament with Pamorelin® LA 3.75 mg may, as with other GnRH analogues, lead to bone loss, osteoporosis and a higher risk of bone fractures, 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 diabetes or if you suffer from heart or vascular 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 Pamorelin® LA 3.75 mg. Symptoms include sudden headache, vomiting, problems with eye sight and paralysis of the eyes.

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

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.

Children

Pamorelin® LA 3.75 mg is not indicated for use in neonates, infants, children and adolescents.

Pregnancy and breast-feeding

Pamorelin® LA 3.75 mg is not for use in women.

Driving and using machines

Even if used as directed Pamorelin® LA 3.75 mg may change reactions to such an extent that the ability to drive or to operate machines is impaired. This is particularly true in combination with alcohol. 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 informations about some of the ingredients of Pamorelin® LA 3.75 mg

This medicinal product contains sodium, but less than 1 mmol (23 mg) sodium per vial. This medicine is almost "sodium-free"and may be taken with a low sodium diet.

3. HOW TO USE PAMORELIN® LA 3.75 mg

Pamorelin® LA 3.75 mg will be administered to you under the supervision of a physician.

Therapy of prostate cancer with Pamorelin® LA 3.75 mg requires longterm treatment.

For locally advanced hormone-dependent prostate cancer during and following radiation therapy, recommended treatment duration is 2-3 years.

The usual dose is 1 vial of Pamorelin® LA 3.75 mg injected subcutaneously or into the muscle once a month (four weeks).

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

If you have the impression that the effect of Pamorelin® LA 3.75 mg is too strong or too weak, contact your doctor or pharmacist.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pamorelin® LA 3.75 mg can cause side effects, although not everybody gets them.

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 (50%), impotence (4%), and decreased libido (3%).
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.

Very common side effects affecting more than 1 in 10 patients:

•Hot flushes
•Weakness
•Excessive sweating

•Back pain
•Pins and needles sensation in the legs

Common side effects affecting more than 1 in 100 patients

•Nausea
• Tiredness, redness, bruising and/or pain at the injection site, 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 more than 1 in 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
•Depression, inability to sleep, irritability, mood swings
•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 more than 1 in 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, flatulence, 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
•Increased body temperature
•Weight loss
•Stiff joints, joint swelling, musculoskeletal stiffness, osteoarthritis
•Memory loss,
•Feeling confused, decreased activity, having a feeling of elation or well-being
•Inability to ejaculate
•Shortness of breath when lying flat
•Blisters
•Nosebleeds
•Low blood pressure

During post-marketing surveillance the following side effects have also been reported: Blurred vision, blood pressure increased, general discomfort, bone pain, anxiety and rapid formation of wheals due to swelling of the skin or mucous membranes.
Your doctor will determine the countermeasures to be taken.

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 PAMORELIN® LA 3.75 mg

Keep out of the reach and sight of children.

Do not use Pamorelin® LA 3.75 mg 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.

The reconstituted suspension must be used immediately.

Do not store above 25 °C.

6. FURTHER INFORMATION

What Pamorelin® LA 3.75 mg contains

The active substance is triptorelin
One vial contains triptorelin embonate equivalent to 3.75 mg of triptorelin.
After reconstitution in 2 ml solvent, 1 ml of reconstituted suspension contains 1.875 mg of triptorelin.

The other ingredients are:
Powder: poly (d,l-lactide-co-glycolide), mannitol, carmellose sodium, polysorbate 80

Solvent: water for injections

What Pamorelin® LA 3.75 mg looks like and contents of the pack

This medicinal product is a powder and solvent for prolonged-release suspension for injection, the powder is a white to off-white powder and the solvent is a clear solution.

Pamorelin® LA 3.75 mg is available in boxes of
1 vial, 1 ampoule and 1 blister containing 1 injection syringe and 2 injection needles
and in packs of
3 vials, 3 ampoules and 3 blisters each containing 1 injection syringe and 2 injection needles.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

For AT and DE:
Ipsen Pharma GmbH
Einsteinstr. 30
D - 76275 Ettlingen
Germany

For NL:
Ipsen Farmaceutica b.v.
Taurus Avenue 33b
2132 LS Hoofddorp
The Netherlands

For DK, FI, NO:
Institut Produits Synthèse (IPSEN) AB
Kista Sience Tower
Färögatan 33
SE- 164 51 Kista
Sweden

Manufacturer responsible for batch release:

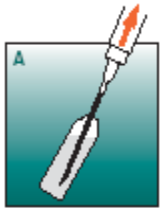
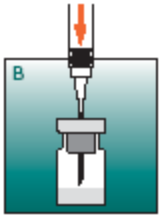
IPSEN PHARMA BIOTECH
Parc d'Activités du Plateau de Signes
chemin départemental N° 402
83870 SIGNES
France

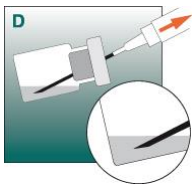
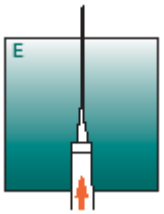
This medicinal product is authorised in the Member States of the EEA under the following names:

Austria and Germany: Pamorelin LA 3,75 mg
Denmark, Finland, Netherlands, Norway: Pamorelin 3,75 mg

This leaflet was last approved in {MM/YYYY}.

The following information is intended for medical or healthcare professionals only:

1 – PREPARATION OF THE INJECTION	
○ The suspension for injection should be prepared immediately before injection. ○ Tap any solution within the tip of the ampoule back into the main body of the ampoule. ○ Tap any powder which has accumulated at the top of the vial back to the bottom of the vial.	
○ Remove the plastic cap from the vial.	
○ Screw a needle onto the syringe (do not remove the needle protection yet!).	
○ Break open the ampoule (dot face up).	
○ Remove the needle protection from the needle and draw up all of the solvent into the syringe.	
○ Insert the needle through the rubber stopper of the vial and inject the solvent slowly, so that, if possible, it washes down the entire upper part of the vial.	
○ Pull up the needle above the liquid level while reconstituting the homogenous, milky injection suspension by swinging the vial gently. Caution: Mixing must not be performed by repeatedly drawing up and discharging the syringe!	

○ Then draw up all of the suspension for injection into the syringe.	
○ Remove the needle. 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	
2 – INJECT	
○ Inject immediately the suspension for injection subcutaneously or intramuscularly. If the suspension for injection is not used immediately in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C.	
3 – AFTER USE	
○ Dispose the needles in designated sharp container. ○ For single use only. Any unused suspension must be discarded.	