

Package leaflet: Information for the patient

Lutrate 3 month Depot 22.5 mg powder and solvent for prolonged-release suspension for injection

Leuporelin acetate

Read all of this leaflet carefully before you are given 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 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lutrate 3 month Depot is and what it is used for
2. What you need to know before you are given Lutrate 3 month Depot
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1. What Lutrate 3 month Depot is and what it is used for

Lutrate 3 month Depot contains the active ingredient leuporelin acetate (also called **leuprolide**), which belongs to a group of medicines called luteinizing hormone releasing hormone (LHRH) agonists (medicines that reduce testosterone – a sex hormone). Lutrate 3 month Depot is a vial containing a white powder, which is made into a suspension for injection into a muscle.

Your doctor has prescribed Lutrate 3 month Depot for the treatment of prostate cancer.

2. What you need to know before you are given Lutrate 3 month Depot

You should not be given Lutrate 3 month Depot:

- if you are allergic to leuporelin acetate, LHRH agonists or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue

- if you have had an orchiectomy (removal of the testicles)
- if you are female or a child
- Lutrate 3 month Depot must not be used alone for the treatment of prostate cancer if the spinal cord is compressed or the cancer has spread to the spine.

Warnings and precautions

Talk to your doctor or nurse before you are given Lutrate 3 month Depot

- your condition may get worse at first during the first weeks of the treatment, but should improve with continued treatment. Such signs and symptoms include: temporary increase of testosterone (a male hormone), hot flushes, bone pain, nervous system disorders (including depression) or urinary obstruction
- if you feel you have experienced an allergic reaction (shortness of breath, asthma, rhinitis, swelling of the face, urticaria, skin eruption), stop using this medicine and inform your doctor
- tell your doctor if you might be at risk or if you have any of the following as you may need more frequent check ups:
 - if you suffer from any unexplained bruising or bleeding or if you feel generally unwell. Although rare, these could be symptoms of changes in the number of red or white cells
 - if you have metabolic disease
 - if you have heart problems or a pounding heart beat
 - if you have diabetes
- your doctor should be aware if you suffer from a bleeding disorder, thrombocytopenia or if you are on treatment with anticoagulants. Your liver function may need to be monitored as changes to the liver and jaundice (yellow eyes and skin) have been reported with leuprorelin treatment
- a fractured spine, paralysis, low blood pressure and high blood pressure have been reported with leuprorelin treatment
- there have been reports of depression in patients taking Lutrate 3 month Depot which may be severe. If you are taking Lutrate 3 month Depot and develop depressed mood, inform your doctor
- a decreased bone density (brittleness or thinning of the bones) has been reported with leuproreline. Your doctor may consider adding an anti-androgen to the treatment with Lutrate 3 month Depot. Your doctor will be on the alert for inflamed veins (thrombophlebitis) and other signs of clotting disorders and oedema (swelling of hands, feet or ankles). There is an increased risk of these occurring in the case that an anti-androgen treatment is added to Lutrate 3 month Depot
- tell your doctor, if you feel pressure on the spinal cord and/or experience urinary disorders and/or notice any blood in your urine (haematuria). In this case your doctor will take if necessary, additional precautions to avoid neurological complications (e.g. tingling in hands and feet,

paralysis) or obstruction of the urethra (the tube that connects the bladder to the outside of the body). You will be closely supervised during the first weeks of treatment

- patients may experience metabolic changes (e.g. glucose intolerance or worsening of existing diabetes), weight changes and cardiovascular disorders
- patients with metabolic or cardiovascular disease and especially patients with history of congestive heart failure (condition in which the heart can no longer pump enough blood to the rest of the body) should be monitored during treatment with leuporelin
- Talk to your doctor, pharmacist or nurse if you have fatty liver
- you will need some blood tests during treatment, to check that Lutrate 3 month Depot is being efficacious
- you may experience a loss of interest in sexual intercourse, hot flushes and occasionally there may be a reduction in size and function of the testes
- you may become fertile again when Lutrate 3 month Depot treatment is stopped
- Lutrate 3 month Depot may interfere with certain laboratory tests so make sure your doctor knows you are using Lutrate 3 month Depot
- seizures can occur in patients with a history of seizures, epilepsy, in patients receiving drugs that can cause seizures and to a lesser extent, in other patients who do not have these characteristics
- please tell your doctor if you have any of the following: 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 Lutrate 3 month Depot.
- If you suffer from a bad or recurrent headache, problems with your eyesight and ringing or buzzing in the ears contact your doctor immediately.
- Severe skin rashes including Stevens-Johnson syndrome, Toxic Epidermal Necrolysis (SJS/TEN) have been reported in association with leuporelin. Stop using leuporelin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Lutrate 3 month Depot

Tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines. It may still be all right for you to be given Lutrate 3 month Depot and your doctor will be able to decide what is suitable for you.

Lutrate 3 month Depot 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, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before you are given this medicine.

Pregnancy

Lutrate 3 month Depot is not indicated for use in women.

This medicine should not be used during pregnancy. Spontaneous abortions may occur if this medicine is administered during pregnancy.

Breast-feeding

This medicine should not be used in breast-feeding women.

Driving and using machines

No specific studies on the effects of Lutrate 3 month Depot on the ability to drive and use machines have been performed.

Disturbance of vision and dizziness can occur during treatment. If affected you should not drive or operate machinery.

Lutrate 3 month Depot contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Lutrate 3 month Depot contains Polysorbate 80

This medicine contains 3,8 mg of polysorbate 80 in each dosage unit. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How Lutrate 3 month Depot will be given to you

Dose

Lutrate 3 month Depot should only be administered by your doctor or a nurse who will also take care of the preparation of the product.

Adults including the elderly:

The recommended dose of Lutrate 3 month Depot is an injection once every three months. The powder is made up into a suspension and given as a single injection intramuscularly (into a muscle) once every three months. The strength of your treatment is decided by your doctor.

The injection site should be varied at regular intervals.

Lutrate 3 month Depot must be administered via the intramuscular route only. Do not administer by another route.

Use in children and adolescents:

Lutrate 3 month Depot is not indicated for use in children and adolescents.

If you receive more Lutrate 3 month Depot than you should

This is unlikely as your doctor or nurse will know the correct dosage. However, if you suspect you have received more than you should, let your doctor know about it immediately so appropriate measures can be taken.

If you miss a dose of Lutrate 3 month Depot

It is important not to miss a dose of Lutrate 3 month Depot. As soon as you realise you have missed an injection contact your doctor who will be able to give you your next injection.

If you stop receiving Lutrate 3 month Depot

Since medical treatment involves administration of Lutrate 3 month Depot for a long period, when the treatment is interrupted you may experience a worsening of the symptoms related to the disease. Therefore, you must not interrupt the treatment prematurely without your doctor's permission.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following symptoms:

- get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).
- Not known (frequency cannot be estimated from available data):
 - If you experience reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome/Toxic Epidermal Necrolysis).
 - Skin redness and itchy rash. (Toxic skin eruption).
 - A skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (Erythema Multiforme).

The following side effects have been reported:

Very common (may affect more than 1 in 10 people):

Hot flushes.

Common (may affect up to 1 in 10 people):

Cold sweats, hyperhidrosis (increased sweating), itching, fatigue, insomnia (not sleeping), decreased sex drive, dizziness, headache, flushing, feeling sick (nausea), diarrhoea, decreased appetite, erectile dysfunction, asthenia (lack or loss of strength), bone pain, pain in the joints and injection site reactions such as skin thickening, injection site pain, erythema (redness of the skin). Urinary tract pain, urine flow decreased, frequent need to urinate especially at night, incomplete bladder emptying, mood changes and depression, changes in liver and muscle blood test values, blood sugar increased and weight gain.

Uncommon (may affect up to 1 in 100 people):

High cholesterol, blood triglyceride increased (high levels of blood lipids), sleep disorders, feeling jittery or anxious, anorexia, taste disturbance, formication (alteration in the skin sensation), lethargy, feeling tired, spinning sensation, blurred vision, chest pain when breathing (pleurisy), ringing in the ears (tinnitus), upper tummy pain, constipation, papule, rash, generalised itching, night sweats, back pain, muscle aching, neck pain, nipple pain, pelvic pain, shrinking of your testicles, testicular disorder, breast swelling or tenderness, ejaculation failure, feeling hot, jaundice, changes in blood test values and changes in ECG (QT prolongation). Injection site reactions such as: hives, warmth and bleeding.

Not known (frequency cannot be estimated from available data)

Inflammation of lungs, lung disease.

Idiopathic intracranial hypertension (increased intracranial pressure around the brain characterised by headache, double vision and other visual symptoms and ringing or buzzing in one or both ears).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly. (see details below)

United Kingdom

The Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lutrate 3 month Depot

Your doctor or pharmacist will know how to store Lutrate 3 month Depot.

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box, vial and pre-filled syringe after "EXP". The syringe has the same expiry date to that of the vial. The expiry date refers to the last day of that month.

Do not store above 25° C. Do not freeze.

Do not throw away any medicines via wastewater. 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 Lutrate 3 month Depot contains

The active substance is leuporelin acetate. Each vial contains 22.5 mg of leuporelin acetate.

The concentration of the reconstituted product is 11.25 mg/ml.

The other ingredients are: Polysorbate 80, Mannitol (E-421), Carmellose sodium (E-466), Triethyl citrate and Poly(lactic acid) (PLA).

The solvent contains (pre-filled syringe): mannitol, water for injection, sodium hydroxide (for pH adjustment) and hydrochloric acid (for pH adjustment).

What Lutrate 3 month Depot looks like and contents of the pack

Lutrate 3 month Depot is white to off-white colour prolonged release powder for use in an injection.

The sterile solvent is clear, colorless and particle free solution which is mixed with powder before injection.

Each pack contains a vial with 22.5 mg of leuporelin acetate, one prefilled syringe with 2 ml of solvent, one adaptor system and one sterile 20 gauge needle.

Marketing Authorisation Holder

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

Ireland: Lutrate 3 month Depot 22.5 mg powder and solvent for prolonged-release suspension for injection United Kingdom: Lutrate 3 month Depot 22.5 mg powder and solvent for prolonged-release suspension for injection

This leaflet was last revised in June 2024.

The following information is intended for healthcare professionals only:

How to prepare the injection?

IMPORTANT: Read and follow carefully each step in the 'Instructions of use' leaflet on the tray including the components of the product kit.

An aseptic technique should be observed during the reconstitution procedure.

Important:

Once mixed, the product must be administered immediately.

This product is for single use only.

Verify the contents of the kit and make sure it includes everything that's mentioned in the leaflet.

The pack contains:

1 (one) vial of Lutrate 3 month Depot 22.5 mg (leuprorelin acetate) powder for suspension for injection

1 (one) pre-filled syringe containing the suspension solvent (mannitol 0.8% solution for injection);

1 (one) single use sterile device for reconstitution including 1 (one) single-use sterile needle.