



Package leaflet: Information for the user

Lutrate 1 month Depot 3.75 mg powder and solvent for prolonged-release suspension for injection

Leuporelin acetate

Read all of this leaflet carefully before you start taking 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

1. What Lutrate 1 month Depot is and what it is used for
2. What you need to know before you use Lutrate 1 month Depot
3. How to use Lutrate 1 month Depot
4. Possible side effects
5. How to store Lutrate 1 month Depot
6. Contents of the pack and other information

1. WHAT LUTRATE 1 MONTH DEPOT IS AND WHAT IT IS USED FOR

Lutrate 1 month Depot is a vial containing a white powder, which is made into a suspension for injection into a muscle. Lutrate 1 month Depot contains the active ingredient leuporelin acetate (also called leuprolide), which belongs to a group of medicines called luteinising hormone releasing hormone (LHRH) agonists (medicines that reduce testosterone – a sex hormone).

Your doctor has prescribed Lutrate 1 month Depot for palliative treatment of advanced prostate cancer.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LUTRATE 1 MONTH DEPOT

Do not use Lutrate 1 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 of 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 1 month Depot must not be used alone for the treatment of prostate cancer when the spinal cord is compressed or the cancer has spread to the spine.

Warnings and precautions

- talk to your doctor or pharmacist before you are given Lutrate 1 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:
 - 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
 - you have metabolic disease
 - you have heart problems, or a pounding heart beat
 - you have diabetes
- your doctor should be aware of any previous personal clinical history of pituitary adenoma (non-cancerous tumour of pituitary). Cases of pituitary apoplexy (partial tissue loss of pituitary gland) have been described after initial administration of this type of drug to patients with pituitary adenoma. Pituitary apoplexy may be manifested by sudden headache, meningismus, visual disturbances or altered vision, even blindness, and occasionally, decrease in the level of consciousness
- 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 leuporelin treatment
- a fractured spine, paralysis, low blood pressure and high blood pressure have been reported with leuporelin treatment

- there have been reports of depression in patients taking Lutrate 1 month Depot which may be severe. If you are taking Lutrate 1 month Depot and develop depressed mood, inform your doctor
- a decreased bone density (brittleness or thinning of the bones) has been reported with leuporelin. Your doctor may consider adding an antiandrogen to the treatment with Lutrate 1 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 antiandrogen treatment is added to Lutrate 1 month Depot
- tell your doctor, if you feel pressure on the spinal cord and/or experience urinary disorders and/or haematuria (blood in the urine). In this case your doctor will be 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
- you will need some blood tests during treatment, to check that Lutrate 1 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 1 month Depot treatment is stopped
- Lutrate 1 month Depot may interfere with certain laboratory tests so make sure your doctor knows you are using Lutrate 1 month Depot
- Lutrate 1 month Depot contains an ingredient which may give a positive test result in doping controls
- convulsions can occur in predisposed patients (those with a history of seizures, epilepsy, cerebrovascular disorders, anomalies or central nervous system tumours), 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 1 month Depot.

Other medicines and Lutrate 1 month Depot

Tell your doctor or pharmacist 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 1 month Depot and your doctor will be able to decide what is suitable for you. Lutrate 1 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, breast-feeding and fertility

Lutrate 1 month Depot is not indicated for use in women. This medicine is contraindicated during pregnancy. Spontaneous abortions may occur if this medicine is administered during pregnancy.

Driving and using machines

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

Lutrate 1 month Depot contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium- free'.

3. HOW TO USE LUTRATE 1 MONTH DEPOT

Dose

Lutrate 1 month Depot must be given under the supervision of a doctor or a qualified health practitioner. Adults including older people: The recommended dose of Lutrate 1 month Depot is an injection once a month. The powder is made up into a

The following information is intended for healthcare professionals only:

How to prepare the injection?

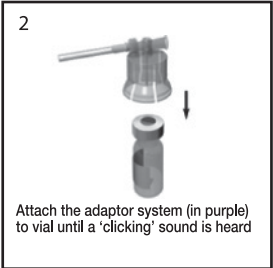
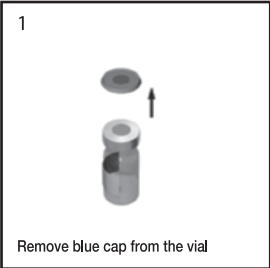
Follow these instructions carefully. An aseptic technique should be observed during the reconstitution procedure.

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 1 month Depot 3.75 mg (leuporelin acetate) powder for suspension for injection
1 (one) pre-filled syringe containing the suspension solvent (mannitol 0.8% solution for injection);
1 (one) device for reconstitution containing 1 (one single use sterile needle);



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Version No.:	XXXXXX/LF/XXX/01
Product Name:	Lutrate 1 month Depot 3.75 mg suspension for injection
Pack Size:	TBC
Component:	Leaflet
SKU:	XXXXXX
Market:	Ireland
Production Site:	GP Pharm
Revision No.:	1
Revision Date:	24/06/2015
Revised by:	PAT

Dimension:	180 x 400 mm
Commodity No.:	N/A
Pharma Code:	N/A
Core Spec Ref:	N/A
DCMF:	N/A
Print Colours:	Black

Non-Print Colours: Cutter

Tech App. Date:	No
Min. Font Size:	8 pt

CRF:	AMCo.CRF.XXX.XXXX
DOA:	N/A
DOI:	N/A

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Name

Date

suspension and given as a single injection intramuscularly (into a muscle) once a month (approximately every 28 to 33 days).
The injection site should be varied at regular intervals.

Lutrate 1 month Depot must be administered via the intramuscular route only. Do not administer by another route.

Use in children and adolescents: Lutrate 1 month Depot is not indicated for use in children and adolescents
The strength of your treatment is decided by your doctor.

If you use more Lutrate 1 month Depot than you should
This is unlikely as your doctor or nurse will not 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 forget a dose of Lutrate 1 month Depot
It is important not to miss a dose of Lutrate 1 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 using Lutrate 1 month Depot
Since the medical treatment involves administration of Lutrate 1 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, pharmacist 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 get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).
The following side effects have been reported:

Very common (may affect more than 1 in 10 people):
Hot flushes and injection site reactions.

Common (may affect up to 1 in 10 people):
Night sweats, cold sweats, fatigue, headache, pyrexia (rise in body temperature), increased appetite, erectile dysfunction, hyperhidrosis (increased sweating), asthenia (lack or loss of strength), back pain and injection site reactions such as pain, irritation, discomfort, erythema (redness of the skin), swelling (increment in size or inflation) bruising (contusion), mood changes and depression in long term use of leuporelin.

Uncommon (may affect up to 1 in 100 people):
Breast swelling, breast tenderness, spinning sensation (vertigo), weakness, sleep disorders, somnolence (sleepiness), insomnia (not sleeping), low tummy pain, diarrhoea, feeling sick (nausea), vomiting, feeling hot and cold, feeling jittery, fever, yellow eyes and skin (jaundice), changes in liver enzymes, anorexia (not eating), high cholesterol, joint pain, muscle spasms, pain in the hands and feet, decreased sex drive, mood alterations, urine retention, frequent need to urinate, uncontrolled urine (incontinence), swelling around the eyes, ejaculation failure, hyperlipidaemia (high levels of blood lipids, pruritus (itching), urticaria (nettle rash), mood changes depression in short term use of leuporelin, changes in ECG (QT prolongation) and injection site reactions such as: swelling, injury and haemorrhage.

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

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. By reporting side effects you can help provide more information on the safety of this medicine.
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

5. HOW TO STORE LUTRATE 1 MONTH DEPOT

Your doctor or pharmacist will know how to store Lutrate 1 month Depot.
Keep this medicine out of sight and reach of children.
Do not store above 25° C. Do not freeze.
Store in the original package, in order to protect from light
Do not use this medicine after the expiry date as indicated 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 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lutrate 1 month Depot contains
The active substance is leuporelin acetate. Each vial contains 3.75 mg of leuporelin acetate.

The concentration of the reconstituted product is 1.8 75 mg/ml.
The other ingredients are: Polysorbate 80, Mannitol (E-421), Carmellose sodium (E-466), Triethyl citrate and Poly(DL-lactide-co-glycolide) (PLGA).
The solvent contains (pre-filled syringe): mannitol, water for injection, sodium hydroxide (for pH adjustment) and hydrochloric acid (for pH adjustment).

What Lutrate 1 month Depot looks like and contents of the pack
Each pack contains a vial with 3.75 mg of leuporelin acetate, one pre-filled syringe with 2 ml of solvent, one adaptor system and one sterile 20 gauge needle.

Marketing Authorisation Holder
Mercury Pharmaceuticals Limited,
Capital House, 1st Floor,
85 King William Street,
London EC4N 7BL,
United Kingdom

Manufacturer
GP-PHARM, S.A.
Pol ind Els Vinyets –els Fogars. Sector 2
Carretera comarcal 244, km22
08777 Sant Quintí de Mediona.
Spain

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

Spain: Leuporelina acetato 3.75 mg polvo y disolvente para suspensión de liberación prolongada inyectable
Ireland: Lutrate 1 month Depot 3.75 mg powder and solvent for prolonged-released suspension for injection
United Kingdom: Lutrate 1 month Depot 3.75 mg powder and solvent for prolonged-released suspension for injection

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Version No.: XXXXXX/LF/XXX/01
Product Name: Lutrate 1 month Depot 3.75 mg suspension for injection
Pack Size: TBC
Component: Leaflet
SKU: XXXXXX
Market: Ireland
Production Site: GP Pharm
Revision No.: 1
Revision Date: 24/06/2015
Revised by: PAT

Dimension: 180 x 400 mm
Commodity No.: N/A
Pharma Code: N/A
Core Spec Ref: N/A
DCMF: N/A
Print Colours: Black

Non-Print Colours: Cutter

Tech App. Date: No
Min. Font Size: 8 pt

CRF: AMCo.CRF.XXX.XXXX
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