Package leaflet: Information for the patient

Lutrate 1 month Depot 3.75 mg powder and solvent for prolonged-release suspension for injection
Leuprorelin 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 1 month Depot is and what it is used for

Lutrate 1 month Depot contains the active ingredient leuprorelin acetate (also called **leuprolide**), which belongs to a group of medicines called luteinizing hormone releasing hormone (LHRH) agonists (medicines that reduce testosterone and estradiol – sex hormones). Lutrate 1 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 1 month Depot for:
- Treatment of prostate cancer in men
- Treatment of early-stage breast cancer in pre and perimenopausal women at higher risk of recurrence.
- Treatment of hormone responsive advanced breast cancer in pre and perimenopausal women.
- Treatment of endometriosis and uterine fibroids.
- Preservation of ovarian function in pre-menopausal women with cancer who are having chemotherapy.

Use in children:

Lutrate 1 month Depot is a synthetic hormone which can be used to reduce the levels of testosterone and estrogen circulating in the body. Lutrate 1 month Depot is used to treat premature puberty which is caused by a release of certain hormones from the pituitary gland (central precocious puberty) in girls under 9 years of age and boys under 10 years of age.

2. What you need to know before you are given Lutrate 1 month Depot

Use in children: Your doctor will make a precise diagnosis of central precocious puberty.

Do not use Lutrate 1 month Depot:

- if you are allergic (hypersensitive) to leuprorelin acetate, or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic (hypersensitive) to similar medicines to leuprorelin (such as gosererlin, triptorelin) or medicines / products related to a natural hormone called gonadotrhophin releasing hormone (GnRH).

An allergic reaction may include rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue.

Do not use Lutrate 1 month Depot:

- **In men with prostate cancer:**

- if you have had an orchiectomy (removal of the testicles).
- Lutrate 1 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.

- **In women:**

- If you are pregnant, planning to become pregnant or are breastfeeding.
- If you have abnormal vaginal bleeding which you have not discussed with your doctor.
- In pre and perimenopausal women receiving Lutrate 1 month Depot for the treatment of breast cancer:
  - your estrogen levels must have been adequately suppressed with Lutrate 1 month Depot before you start treatment with an aromatase inhibitor such as exemestane and should be checked every three months during combination treatment with Lutrate 1 month Depot and an aromatase inhibitor (see 'Warnings and precautions' section below for more information).

- **In girls with central precocious puberty**

- if the girl to be treated is pregnant or breast-feeding.
- if the girl has abnormal vaginal bleeding which has not been discussed with her doctor (see Warnings and Precaution section below).

Warnings and precautions

When you or your child begin treatment with Lutrate 1 month Depot, existing symptoms may initially get worse as a result of levels of sex steroids in the body increasing. These worsening symptoms usually subside with continued use of Lutrate 1 month Depot (see section 4 for further information).

Talk to your doctor or nurse before you are given Lutrate 1 month Depot

Men, women and children:

- If you or your child have a seizure (fit) tell your doctor. There have been reports of seizures in patients receiving Lutrate 1 month Depot. These occurred in patients with or without epilepsy or other reasons that increase the risk of having seizures.
- If you or your child develop depressed mood, tell your doctor. There have been reports of depression in patients receiving Lutrate 1 month Depot, which may be severe.
- If you (or your child) suffer from a bad or recurrent headache, problems with your eyesight and ringing or buzzing in the ears contact your doctor immediately.

Both men and women:

- If you have diabetes, tell your doctor. Lutrate 1 month Depot can cause changes in blood glucose levels and your blood sugar levels may need to be monitored more frequently.
- If during treatment with Lutrate 1 month Depot you develop signs of diabetes, which include feeling very tired, losing weight, feeling very thirsty or needing the toilet more frequently than usual, tell your doctor. Your doctor may need to monitor your blood sugar levels
- If you have heart problems, tell your doctor. Lutrate 1 month Depot may cause changes in blood pressure or blood fats (lipids or cholesterol) and may increase the risk of developing heart problems. Your doctor may monitor you during treatment or monitor you more frequently.
- If during treatment with Lutrate 1 month Depot you develop signs of heart problems, which include having chest pain, irregular heartbeat, nausea, fatigue or severe headache, tell your doctor. Your doctor may monitor you.
- If you are at an increased risk of thinning of the bones (osteoporosis) you should tell your doctor before taking Lutrate 1 month Depot. Lutrate 1 month Depot may cause thinning of the bones. Risk factors 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).

Women only:

- If you are a woman with submucous fibroids (benign tumours in the muscle underneath the lining of the womb), Lutrate 1 month Depot can cause severe bleeding when the fibroids breakdown. Contact your doctor immediately if you experience severe or unusual bleeding or pain.
- If you are a woman and continue to have periods (menstruate) after starting treatment with Lutrate 1 month Depot you should tell your doctor.
- If you are a woman of child-bearing age, you should use non hormonal contraception, whilst receiving Lutrate 1 month Depot. Although Lutrate 1 month Depot causes periods to stop, it is not itself a contraceptive. If you are unsure about this, speak to your doctor.
- If you are being given Lutrate 1 month Depot for the treatment of breast cancer:
    - Your doctor may assess your bone density and ovarian function before you start treatment with Lutrate 1 month Depot and monitor your bone density and ovarian function throughout treatment.
    - Lutrate 1 month Depot must be started at least 6-8 weeks before you start treatment with an aromatase inhibitor and should continue throughout treatment with the aromatase inhibitor.
    - If you have had chemotherapy, Lutrate 1 month Depot treatment should only commence once you have completed chemotherapy and pre-menopausal status has been confirmed.
    - The recommended duration of treatment with Lutrate 1 month Depot in combination with other hormone treatments for breast cancer is up to 5 years.
    - If you are being given Lutrate 1 month Depot in combination with an aromatase inhibitor, your doctor may monitor your blood pressure, heart function and blood glucose levels during treatment. If you have depression or a history of depression, please inform you doctor so that they can additionally monitor your symptoms of depression during treatment with Lutrate 1 month Depot.
    - If you are unsure about this, speak to your doctor.

Men only:

- In the rare event of an abscess at the injection site your doctor may measure your testosterone levels as there could be reduced absorption of leuprorelin from the injection site.
- If you are a man with urinary obstruction or spinal cord compression due to your prostate cancer spreading. Your doctor will supervise you closely for the first few weeks of treatment. If you

experience difficulty passing urine, bone pain, weakness of lower limbs or pins and needles you should tell your doctor.
- Please 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 Lutrate 1 month Depot.

In children:
- In the event of a sterile abscess at the injection site your doctor will monitor your hormone levels as there could be reduced absorption of leuprorelin from the injection site.
- If the child has progressive brain tumour your doctor will decide if treatment with leuprorelin is appropriate.

In girls with central precocious puberty:
- After the first injection vaginal bleeding (spotting) and discharge may occur as a sign of hormone withdrawal. Vaginal bleeding beyond the first/second month of treatment needs to be investigated.
- Bone density may decrease during treatment of central precocious puberty with Lutrate 1 month Depot. However, after treatment is stopped, subsequent bone mass growth is preserved and peak bone mass in late adolescence does not seem to be affected by treatment.
- Discontinuation of treatment may lead to a slipping of the growth plate of the thigh bone. A possible cause could be a weakness of the growth plate due to a lower concentration of female sexual hormones during treatment.

Other medicines and Lutrate 1 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 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 and breast-feeding
Lutrate 1 month depot must not be administered in pregnant or breast-feeding women or girls (see also section “Do not use Lutrate 1 month depot

Driving and using machines
No specific studies on the effects of Lutrate 1 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 1 month Depot contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium- free’.

3. How Lutrate 1 month Depot will be given to you

Dose
Lutrate 1 month Depot must only be administered by your doctor or a nurse who will also take care of the preparation of the product.

Adults including elderly:
The recommended dose of Lutrate 1 month Depot is an injection once a month. The powder is made up into a suspension and given as a single injection intramuscularly (into a muscle) once a month (approximately every 28 to 33 days). The strength of your treatment is decided by your doctor.
The injection site should be varied at regular intervals.

If you have early breast cancer, you will be given Lutrate 1 month Depot once a month in combination with tamoxifen or an aromatase inhibitor. A minimum of two injections of Lutrate 1 month Depot with one month between each injection should be given before you start treatment with an aromatase inhibitor or tamoxifen.

If you have advanced breast cancer, you will be given Lutrate 1 month Depot once a month as an add-on to your other breast cancer treatment.

If you have endometriosis, you will be given an injection of Lutrate 1 month Depot for a period of up to 6 months only and treatment will be initiated during the first five days of the menstrual cycle. Treatment with Lutrate 1 month Depot may be extended to up to 12 months if you are also having hormone replacement therapy (HRT).

If you have uterine fibroids, you will be given an injection of Lutrate 1 month Depot once a month usually for 3-4 months before surgery.

If you are being given Lutrate 1 month Depot to preserve ovarian function whilst receiving chemotherapy, you will normally be given one injection of Lutrate 1 month Depot two weeks before starting chemotherapy and then every month for the duration of your chemotherapy treatment.

Use in children
Treatment of children should be under the overall supervision of the paediatric endocrinologist.
The dosing scheme needs to be adapted individually.
The recommended starting dose is dependent on the body weight:

a) Children with a body weight 20 kg or more

Unless prescribed otherwise, 2 ml Lutrate 1 month Depot (3.75 mg leuprorelin acetate) is administered once a month as a single intramuscular injection.

b) Children with a body weight less than 20 kg

Taking into account the clinical activity of the central precocious puberty in these rare cases, the following applies:

Unless prescribed otherwise, 1 ml Lutrate 1 month Depot (1.88 mg leuprorelin acetate) are administered once a month as a single intramuscular injection. The remainder of the suspension should be discarded. Your doctor will monitor the child's weight gain.

Depending on the central precocious puberty activity, your doctor may increase the dosage in the presence of inadequate suppression (e.g. vaginal bleeding). Your doctor will determine the minimal effective dose with the help of a blood test.

It is recommended to use the lowest volumes possible for injections in children in order to decrease the inconvenience which is associated with the intramuscular injection.

Sterile abscesses at the injection site often occurred when leuprorelin acetate was administered intramuscularly at higher than the recommended dosages. Therefore, in such cases the absorption of leuprorelin acetate from the depot can be decreased (see section 4.4).

If any sign of swelling or abscess forms at the injection site, your doctor should be informed straight away.

The duration of treatment depends on the clinical signs at the start of treatment or during the course of treatment and is decided by your doctor together with the legal guardian and, if appropriate, the treated child. Your doctor will determine the bone age of the child in regular intervals.

In girls with bone maturation of older than 12 years and boys with bone maturation of older than 13 years your doctor will consider discontinuing the treatment, depending on the clinical effects in your child.

In girls, pregnancy should be excluded before the start of treatment. The occurrence of pregnancy during treatment cannot be generally excluded. In such cases, please talk to your doctor.

The therapy is a long-term treatment, adjusted individually. Please arrange with your doctor that Lutrate 1 month Depot is administered as precisely as possible in regular monthly periods. An exceptional delay of the injection date for a few days (30 ± 2 days) does not influence the result of the therapy.

If you receive more Lutrate 1 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 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.

Women only:
If a Lutrate 1 month Depot injection is missed, breakthrough bleeding or ovulation may occur with the potential for conception. If you think you may be pregnant you should stop using Lutrate 1 month Depot and contact your doctor immediately.

If you stop receiving Lutrate 1 month Depot
Since 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 are being given Lutrate 1 month Depot for the treatment of advanced or early breast cancer, you must not stop your treatment with Lutrate 1 month Depot whilst you are taking an aromatase inhibitor or tamoxifen.

If you are going to discontinue treatment with Lutrate 1 month Depot, your aromatase inhibitor treatment must also be discontinued within 1 month of your last Lutrate 1 month Depot injection.

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.

Contact your doctor immediately or go to hospital:
- If you develop a severe rash, itching, shortness of breath or difficulty breathing. These could be symptoms of a severe allergic reaction.
- If you have severe difficulty breathing, you are coughing up blood or your heart is beating very fast. These could be signs of a pulmonary embolism.

Tell your doctor:

- If you get a severe headache which does not get better when you take painkillers.
- If you suffer from any unexplained bruising or bleeding or feel generally unwell whilst using Lutrate 1 month Depot. Although rare, these could be symptoms of changes in the number of red or white blood cells

If you get any side effects talk **to your doctoror nurse. This includes any side effects not listed in this leaflet.**

Possible side effects in <u>men:</u>

- When men with prostate cancer first start treatment with Lutrate 1 month Depot, levels of testosterone can increase and in some people this may cause a temporary increase in urinary symptoms. In men with spinal cord compression, you may additionally experience bone pain, weakness in your lower limbs or pins and needles. In some cases, to prevent this from happening, your doctor may give you another type of drug such as cyproterone acetate or flutamide before and just after your first Lutrate 1 month Depot injection. **If you do get worsening pain, weakness or loss of feeling in your legs or difficulty passing urine, contact your doctor immediately**.
- If you have an existing pituitary lesion, there may be an increased risk of loss of blood to the area, which may cause permanent damage. This is very rare (may affect more than 1 in 10,000 people).
- Blood sugar levels may be altered during treatment with Lutrate 1 month Depot, which may affect control in diabetic patients and require more frequent monitoring.
- If you have a blood test your doctor may notice a change in blood fat (lipids or cholesterol) levels or in values for tests on how the liver is working. These changes do not usually cause any symptoms.

The following safety profile of Lutrate 1 month Depot is based on the results of a phase III clinical trial in prostate cancer patients:

<u>Very common (may affect more than 1 in 10 people)</u>:
Hot flushes

<u>Common (may affect up to 1 in 10 people)</u>:
Night sweats, cold sweats, fatigue, headache, fever, decreased appetite, erectile dysfunction, increased sweating(hyperhidrosis), asthenia (lack or loss of strength), back pain and injection site reactions such as pain, irritation, discomfort, erythema (redness of the skin), swelling, bruising (contusion)

<u>Uncommon (may affect up to 1 in 100 people)</u>:
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, 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, incomplete bladder emptying, frequent need to urinate, uncontrolled urination (incontinence), swelling around the eyes, ejaculation failure, hyperlipidaemia (high levels of blood lipids, pruritus (itching), urticaria (nettle rash), mood changes depression, changes in ECG (QT prolongation) and injection site reactions such as: swelling, injury and bleeding.

<u>Not known (frequency cannot be estimated from available data):</u>
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)

Other adverse events which have been reported to occur with leuprorelin acetate treatment include:
weight changes, muscle weakness, bone pain, a reduction in size and function of the testes, tiredness, loss of appetite, depression, mood changes (with long-term use), abnormalities in liver function or liver blood tests, swelling of the breast tissue or swelling in your ankles or hands, dizziness, tingling in the hands or feet, muscle ache or weakness in the legs, blood tests may show anaemia (low red cell counts), low counts in white cells or platelets, allergic reactions (may include symptoms of rash, itching, wheals or a serious allergic reaction which causes difficulty breathing or dizziness), changes in blood fats (lipids or cholesterol) or blood sugar, paralysis, seizure, altered vision, pounding heartbeats, blood clots in lungs, high or low blood pressure, jaundice, fracture of the spine, thinning of bone, difficulty passing urine, fever, chills, in patients with existing tumours of the pituitary gland, bleeding of the pituitary gland may occur.

Possible side effects in women:

- When women first start treatment with Lutrate 1 month Depot, levels of sex steroids can increase and in some people this may cause a temporary increase in symptoms. These symptoms will stop with continued treatment.

- Many of the side effects of Lutrate 1 month Depot are related to the decrease in estrogen level. Estrogen level returns to normal after treatment is stopped. Common side effects include hot flushes, mood swings, depression and vaginal dryness. As can happen naturally when women reach the menopause, Lutrate 1 month Depot can cause a small amount of bone thinning. Vaginal bleeding may occur during treatment.

- If you have an existing pituitary lesion, there may be an increased risk of loss of blood to the area, which may cause permanent damage. This is very rare (may affect more than 1 in 10,000 people).

- Blood sugar levels may be altered during treatment with Lutrate 1 month Depot, which may affect control in diabetic patients and require more frequent monitoring.

- If you have a blood test your doctor may notice a change in blood fat (lipid or cholesterol) levels or in values for tests on how the liver is working. These changes do not usually cause any symptoms

Very common (may affect more than 1 in 10 people):
Difficulty sleeping, headaches, hot flushes or bone pain

Common (may affect up to 1 in 10 people):
Weight changes, mood changes (with long-term use), depression, tingling in hands or feet, dizziness, nausea, joint pain, muscle weakness, breast tenderness, changes in breast size, vaginal dryness, excessive swelling, swelling in ankles or skin reactions at the injection site (these include skin hardening, redness, pain, abscesses, swelling, nodules, ulcers and skin damage) .

Uncommon (may affect up to 1 in 100 people):
Loss of appetite, mood changes (with short-term use), changes in blood fats (lipids or cholesterol), altered vision, pounding heartbeats, diarrhoea, vomiting, abnormalities in liver blood tests, hair loss, muscle aches, fever, or tiredness.

Very rare (may affect up to 1 in 10,000 people):
In patients with existing tumours of the pituitary gland, bleeding of the pituitary gland may occur.

Not known (frequency cannot be estimated from the available data):
Blood tests may show anaemia (low red cell counts), low counts in white cells or platelets, allergic reactions (may include symptoms of rash, itching, wheals or a serious allergic reaction causing difficulty breathing or dizziness), changes in blood sugar, paralysis, blood clots in the lungs, high or low blood pressure, jaundice, abnormalities in liver function, fracture of the spine, seizure, thinning of bone or vaginal bleeding, inflammation of the vagina (which can cause itching, discomfort and discharge), reduced sex drive, chills, inflammation of lungs or 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)

Side effects when used in women for breast cancer in combination with either tamoxifen or an aromatase inhibitor
The following side effects have been seen when a similar class of medicine called LHRH analogues (Luteinizing hormone releasing hormone analogues) has been used for breast cancer in combination with either tamoxifen or an aromatase inhibitor:

Very common (may affect more than 1 in 10 people):
Nausea, feeling very tired, joint and muscle pain, osteoporosis, hot flushes, excessive sweating, difficulty in sleeping, depression, decreased libido, dryness of the vagina, pain during or after sexual intercourse, urinary incontinence, increased blood pressure.

Common (may affect up to 1 in 10 people):
Diabetes, high blood sugar (hyperglycaemia), pain, bruising, redness and swelling at injection site, allergic reaction, bone fractures, blood clot in a blood vessel.

Uncommon (may affect up to 1 in 100 people)
Bleed in the brain, lack of blood supply to the brain or the heart.

Rare (may affect up to 1 in 1000 people)
Change in ECG (QT prolongation)

Possible side effects in children
In the initial phase of treatment, a short-term rise in the sex hormone levels occurs, followed by a fall to values within the prepuberty range. Due to this effect, side effects may occur particularly at the start of treatment.

Common (may affect up to 1 in 10 people):
Mood swings, depression, headache, abdominal pain / abdominal cramps, feeling sick / vomiting, acne, vaginal bleeding, spotting, discharge, injection site reactions (these include skin hardening, redness, pain, abscesses, swelling, nodules, ulcers and skin damage).

Very rare (may affect up to 1 in 10,000 people):
General allergic reactions (symptoms include fever, rash, itching, wheals or chills).
Sserious allergic reaction which causes difficulty in breathing or dizziness. If this happens, contact your doctor immediately or go to the hospital.

In patients with existing tumours of the pituitary gland, bleeding of the pituitary gland may occur.

Not known (frequency cannot be estimated from the available data):
Seizure, 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)

Notes:
In general, if vaginal bleeding (spotting) occurs with continued treatment (after possible withdrawal bleeding in the first month of treatment), this may be a sign of potential underdosage. Please tell your doctor if vaginal bleeding occurs.

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
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 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 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^{o} C. Do not freeze.

Store in the original package in order to protect from light

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

The concentration of the reconstituted product is 1.875 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
Lutrate 1 month Depot is white to off-white colour prolonged release powder for use in an injection .

The sterile solvent is clear transparent solution which is mixed with powder before injection.

Each pack contains a vial with 3.75 mg of leuprorelin acetate, one prefilled syringe with 2 ml of solvent, one adaptor system and one sterile 20 gauge needle.

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

Ireland: Lutrate 1 month Depot 3.75 mg powder and solvent for prolonged-release suspension for injection United Kingdom: Lutrate 1 month Depot 3.75 mg powder and solvent for prolonged-release suspension for injection

This leaflet was last revised in 07/2022.

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 1 month Depot 3.75 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) sterile needle