**INFORMATION ABOUT TREATMENT WITH LEUPRORELIN TO LOWER TESTOSTERONE LEVELS IN GENDER DYSPHORIA**

**(Brand Name is PROSTAP 3)**

**Read all of the information in this leaflet, before you start using this medicine because it contains important information for you.**

* If you have any further questions, ask your clinician or GP (doctor or pharmacist)
* This medicine has been prescribed for you. Do not pass it on to others. (It may harm them, even if their condition is the same as yours).
* If you get any side effects talk to your clinician or GP (doctor or pharmacist)

**This leaflet includes information on the following;**

1. What Leuprorelin is and what it is used for
2. What you need to know before you use Leuprorelin
3. How to use Leuprorelin
4. Possible side effects
5. How to store Leuprorelin

**1. WHAT LEUPRORELIN IS AND WHAT IT IS USED FOR**

Leuprorelin is a synthetic hormone (also known as a Gonadotrophin Releasing Hormone agonist or GnRHa) which can be used to reduce the levels of testosterone circulating in the body. It may be given alone, or alongside oestrogen, to improve feminisation by helping to:

Reduce the amount of body and facial hair

Reduce sex drive

Reduce erectile activity

Reduce muscle size and strength

***Note****: Leuprorelin is also used to treat prostate cancer in men and to treat hormone responsive early stage breast cancer in pre and perimenopausal women at higher risk of recurrence and hormone responsive advanced breast cancer in pre and perimenopausal women. It is also used in women to treat endometriosis.*

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE LEUPRORELIN**

* **Do not take Leuprorelin** If you are allergic (hypersensitive) to Leuprorelin Acetate (PROSTAP SR or PROSTAP 3) or any of the other ingredients of PROSTAP 3

**Leuprorelin should be used with caution and only after a full discussion of risks:**

* If you have diabetes, Leuprorelin can aggravate existing diabetes therefore diabetic patients may need more frequent monitoring of blood glucose levels.
* If you have diabetes or have an increased risk of thinning of the bones (osteoporosis) you should tell your doctor before taking Leuprorelin.

***Note:*** *The frequency on the effect on diabetes is unknown and bone thinning is not an issue if you are prescribed sex hormones at the same time as Leuprorelin.*

**Risk factors for osteoporosis 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 medication for epilepsy or have taken oral steroids such as Hydrocortisone or Prednisolone for a long time.

There have been reports of depression in patients taking Leuprorelin which may be severe. If you are taking Leuprorelin and develop depressed mood, inform your clinician or GP.

***Note:*** *Anecdotal reports from some patients suggest an increase in depressed/low mood a week after the injection is administered*

**Other medicines and Leuprorelin.**

Please tell your clinician or GP if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Leuprorelin 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, Moxifloxacin and antipsychotics.

**Leuprorelin with food and drink**

The injection is not affected by food or drink and can therefore be administered at any time.

**Driving and using machines**

Do not drive or operate machinery if you experience drowsiness, dizziness or visual disturbances whilst being treated with Leuprorelin.

**3. HOW TO USE LEUPRORELIN**

**It is administered by injection only**

The doctor or nurse will give you an injection of Leuprorelin. The injection will normally be given in your arm, thigh or abdomen. The injection site should be varied at regular intervals.

You will normally be given an injection once every 3 months.

An exceptional delay of the injection date for a few days does not influence the result of the therapy.

***Note:*** *Anecdotal reports from some patients suggests soreness at injection site, which tends to be more when it’s injected in the arm*

**If you miss an injection**

As soon as you realise you have missed an injection, contact your doctor who will be able to give you your next injection. You do not need to take extra or increase the dose.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Leuprorelin can cause side effects, although not everybody will suffer from them.

**Contact your doctor immediately or go to hospital if you develop the following:**

* Severe rash, itching, shortness of breath or difficulty breathing following the administration of Leuprorelin as these symptoms could be symptoms of a severe allergic reaction.

**Tell your GP:**

* 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 taking Leuprorelin. Although rare, these could be symptoms of changes in the number of red or white blood cells.

**If you notice any side effects below or side effects that are not listed in this document, speak to your doctor / pharmacist / prescriber:**

**When using Leuprorelin to lower your testosterone level:**

In the first few weeks after starting treatment with Leuprorelin levels of testosterone can increase and in some people this may cause a temporary increase in sex drive, erections and body hair. If you are particularly concerned about the potential increase in testosterone effects – discuss with this with your prescriber as they may prescribe another drug short term to reduce these types of effects.

* Blood sugar levels may be altered during treatment with Leuprorelin, 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 lipid (cholesterol) levels or in values for tests on how your liver is working. These changes do not usually cause any symptoms.

**Very common side-effect (may affect more than 1 in 10 people):**

* weight changes
* hot flushes (should not be an issue if taking sex hormones)
* sweating (should not be an issue if taking sex hormones)
* muscle weakness
* bone pain
* reduced sex drive
* inability to have an erection
* reduction in size and function of the testes
* tiredness
* skin reactions at the injection site (these include skin hardening, redness, pain, abscesses, swelling, nodules, ulcers and skin damage).

**Common side-effect (may affect more than 1 in 10 people):**

* loss of appetite
* difficulty sleeping
* depression / mood changes (with long-term use)
* headache
* nausea
* abnormalities in liver function or liver blood tests
* joint pain
* swelling of the breast tissue or swelling in your ankles.

**Uncommon side-effects (may affect up to 1 in 100 people):**

* mood changes (with short-term use)
* dizziness
* tingling in the hands or feet
* diarrhoea
* vomiting
* muscle ache or weakness in the legs.

**The following side-effects have also been reported with use of Leuprorelin**, but the frequency of the events is unknown as the data is limited:

* anaemia (low red cell counts), low counts in white cells or platelets (these would show up through blood tests)
* allergic reactions (may include symptoms of rash, itching, wheals or a serious allergic reaction which causes difficulty breathing or dizziness)
* changes in blood lipids (cholesterol) or blood sugar
* paralysis
* seizure
* altered vision
* pounding heartbeats
* changes in ECG (QT prolongation)
* blood clots in lungs
* high or low blood pressure
* jaundice
* fracture of the spine
* thinning of bone
* difficulty passing urine
* fever/chills
* inflammation of lungs or lung disease
* loss of appetite,

**Reporting of side effects:**

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

**5. HOW TO STORE LEUPRORELIN**

* Keep out of the sight and reach of children.
* Do not use this medicine after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
* Do not store above 25°C.
* Do not refrigerate or freeze.
* Store in the original container in order to protect from light.
* Once mixed with the Sterile Solvent, the suspension must be used immediately.
* If the pack has been opened or damaged, return it to your pharmacist.
* 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.