

PACKAGE LEAFLET: INFORMATION FOR THE USER
PROSTAP® 3 DCS

**11.25 mg Powder and Solvent for Prolonged-release
Suspension for Injection in Pre-filled Syringe**

Leuporelin acetate

Read all of this leaflet carefully before you start using 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 pharmacist.
- 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT PROSTAP 3 IS AND WHAT IT IS USED FOR

PROSTAP 3 is a synthetic hormone which can be used to reduce the levels of testosterone and estrogen circulating in the body.

PROSTAP 3 is used to treat prostate cancer in men and endometriosis and uterine fibroids in women.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROSTAP 3

PROSTAP 3 is not recommended for use in children under the age of 18 years.

Do not take PROSTAP 3:

- If you are allergic (hypersensitive) to leuporelin acetate (PROSTAP SR, PROSTAP 3 or PROSTAP 6) or any of the other ingredients of PROSTAP 3 (listed in section 6).
- If you are a man with prostate cancer, and have had injections of a synthetic hormone in the past that has not worked, or you have had an operation to remove your testicles.
- 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.

Warnings and precautions:

Both men and women:

- If you are diabetic PROSTAP 3 can aggravate existing diabetes therefore diabetes patients may need more frequent monitoring of the blood glucose levels.
- If you suffer from heart problems you should tell your doctor.
- If you are at an increased risk of thinning of the bones (osteoporosis) you should tell your doctor before taking PROSTAP 3. 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 drugs for epilepsy or have taken steroids such as hydrocortisone or prednisolone for a long time.
- There have been reports of depression in patients taking PROSTAP 3 which may be severe. If you are taking PROSTAP 3 and develop depressed mood, inform your doctor.

Women only:

- If you are a woman with submucous fibroids (benign tumours in the muscle underneath the lining of the womb), PROSTAP 3 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 PROSTAP 3 you should tell your doctor.
- If you are a woman of child-bearing age, you should use non hormonal contraception, whilst receiving PROSTAP 3. Although PROSTAP 3 causes periods to stop, it is not itself a contraceptive. If you are unsure about this talk 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 leuporelin from the injection site.
- If you are a man with urinary obstruction or spinal cord compression. Your doctor will supervise you closely for the first few weeks of treatment.

Other medicines and PROSTAP 3

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

PROSTAP 3 with food and drink

PROSTAP 3 can be taken with or without food.

Pregnancy and breastfeeding

You should not take PROSTAP 3 if you are pregnant, planning to become pregnant or are breastfeeding.

Driving and using machines

Do not drive or operate machinery if you experience drowsiness, dizziness or visual disturbances whilst being treated with PROSTAP 3.

3. HOW TO TAKE PROSTAP 3

The doctor or nurse will give you an injection of PROSTAP 3. 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.

If you have endometriosis you will be given an injection of PROSTAP 3 for a period of 6 months only and treatment will be initiated during the first five days of the menstrual cycle.

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.

Women only:

If a PROSTAP 3 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 PROSTAP 3 and contact your doctor immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PROSTAP 3 can cause side effects, although not everybody gets them.

Contact your doctor immediately or go to hospital:

- If you develop a severe rash, itching or shortness of breath or difficulty breathing. These could be symptoms of a severe allergic reaction.

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 taking PROSTAP 3. 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 doctor or pharmacist. This includes any side effects not listed in this leaflet

Very Common (affects more than 1 in 10 people)

- Weight gain
- Hot flushes
- Loss of interest in sexual intercourse (men only)
- Reduction in size and function of the testes (men only)
- Tiredness
- Sweating

Common (affects less than 1 in 10 people)

- Loss of appetite
- Depression
- Mood changes
- Headache
- Nausea
- Vomiting
- Muscle weakness
- Pain in the joints
- Swelling of the breasts (men only)
- Swelling in your ankles
- Difficulty sleeping
- Tingling in the hands or feet
- Change in values for tests on how the liver is working. These changes do not usually cause any symptoms.

Uncommon (affects less than 1 in 100 people)

- Anaemia
- Fever or chills
- Weight loss
- Increase in blood pressure
- Decrease in blood pressure
- Diarrhoea

Rare (affects less than 1 in 1000)

- Blood sugar levels may be altered during treatment with PROSTAP 3, which may affect control in diabetic patients and require more frequent monitoring.
- Dizziness
- Hair loss (women only)
- Skin reactions at the injection site have been reported rarely following injection of leuporelin. These include: skin hardening, redness, pain, abscesses, swelling, nodules, ulcers and skin damage.

Very rare (affects less than 1 in 10,000 people)

- 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.

Other side effects (how often they happen is not known)

- If you suffer from depression, this may become worse when receiving PROSTAP 3.
- Thinning of bones
- Muscle aching
- Change in breast size or breast tenderness (women only)
- Pounding heartbeats
- Altered vision
- Abnormalities in liver function
- Jaundice
- Change in blood lipid (cholesterol) levels
- Vaginal dryness (women only)
- Blood clot in the lungs which causes chest pain and breathlessness
- Inflammation of the lungs which causes breathlessness, cough and raised temperature
- Reduction in blood platelets, which increases risk of bleeding or bruising
- Decrease in number of white blood cells
- When men with prostate cancer first start treatment with PROSTAP 3, levels of testosterone can increase and in some people this may cause a temporary increase in local pain. 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 PROSTAP 3 injection. If you do get worsening pain, weakness or loss of feeling in your legs or difficulty passing urine, contact your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. HOW TO STORE PROSTAP 3

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after EXP. 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What PROSTAP 3 contains:**

- The active ingredient in PROSTAP 3 powder is leuporelin acetate (11.25 mg).
- The other ingredients in PROSTAP 3 are: poly (DL-lactic acid) and mannitol (E421).
- The Sterile Solvent contains carmellose sodium, mannitol (E421), polysorbate 80, glacial acetic acid and water for injections.

What PROSTAP 3 looks like and contents of the pack:

PROSTAP 3 is a prolonged release powder for use in an injection.

The Sterile Solvent is a clear liquid, which is mixed with the PROSTAP 3 Powder before injection.

Each pack contains one pre-filled dual chamber syringe, containing 11.25 mg of leuporelin acetate in the front chamber and 1 ml of Sterile Solvent in the rear chamber, sealed in a plastic tray.

Procured from within the EU by the Parallel Product Authorisation Holder

Clear Pharma Limited, 157-173 Roden Street, Belfast BT12 5QA, UK.

Manufacturer

Takeda Italia S.p.A., Via Crosa 86, 28065 Cerano, Italy.

Repackager

Pharmaram Limited, Tom Bill Way, Ashby de la Zouch, Leicestershire LE65 2UY, UK.

This leaflet does not contain the complete information about your medicine. If you have any questions or you are not sure about anything you should ask your doctor or pharmacist who can give you more information. The information in this leaflet applies only to PROSTAP 3.

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