

PACKAGE LEAFLET: INFORMATION FOR THE USER

PROSTAP® 6 DCS

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

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

1. WHAT PROSTAP 6 IS AND WHAT IT IS USED FOR

PROSTAP 6 is a synthetic hormone, which can be used to reduce levels of testosterone (sex steroid) circulating in the body. PROSTAP 6 is used to treat prostate cancer in men.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROSTAP 6

PROSTAP 6 is not recommended for use in children under the age of 18 years.

Do not take PROSTAP 6:

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

Warnings and precautions:

When you begin treatment with PROSTAP 6, 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 PROSTAP 6 (see section 4 for further information).

Severe skin rashes including Stevens-Johnson syndrome, Toxic Epidermal Necrolysis (SJS/TEN) have been reported in association with leuprorelin. Stop using leuprorelin and seek medical attention

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immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Talk to your doctor or nurse before being given PROSTAP 6:

- If you have a seizure (fit) tell your doctor. There have been reports of seizures in patients receiving PROSTAP 6. These occurred in patients with or without epilepsy or other reasons that increase the risk of having seizures.
- If you develop depressed mood, tell your doctor. There have been reports of depression in patients receiving PROSTAP 6, which may be severe.
- If you have diabetes, tell your doctor. PROSTAP 6 can cause changes in blood glucose levels and your blood sugar levels may need to be monitored more frequently.
- If during treatment with PROSTAP 6 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. PROSTAP 6 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 PROSTAP 6 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 PROSTAP 6. PROSTAP 6 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).
- If you suffer from a bad or recurrent headache, problems with your eyesight or buzzing in the ears contact your doctor immediately.
- 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 PROSTAP 6.
- If you have a fatty liver.

Other medicines and PROSTAP 6

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. PROSTAP 6 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 breastfeeding

PROSTAP 6 is not indicated for use in women.

Driving and using machines

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Do not drive or operate machinery if you experience tiredness, dizziness or visual disturbances whilst being treated with PROSTAP 6.

PROSTAP 6 contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per injection, that is to say it is essentially 'sodium free'.

3. HOW TO USE PROSTAP 6

PROSTAP 6 should only be administered by your doctor or a nurse who will also take care of the preparation of the product.

The doctor or nurse will give you an injection of PROSTAP 6. 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 6 months.

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PROSTAP 6 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.
- 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 as soon as possible:

- 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 6. 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 increase
- Hot flushes
- Loss of interest in sexual intercourse
- Inability to have an erection
- Reduction in size and function of the testes
- Tiredness
- Sweating

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- Skin reactions at the site of the injection, including skin hardening, redness, pain, swelling.

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
- Swelling in your ankles or hands
- 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
- Allergic reactions (may include symptoms of rash, itching, wheals)

Rare (affects less than 1 in 1000)

- Blood sugar levels may be altered during treatment with PROSTAP 6, which may affect control in diabetic patients and require more frequent monitoring.
- Dizziness
- Skin reactions at the injection site, including abscesses, nodules, ulcers and skin damage.

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

- Serious allergic reaction causing difficulty breathing or dizziness. If this happens, contact your doctor immediately or go straight to 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)

- Thinning of bones
- Muscle aching
- Pounding heartbeats
- Altered vision
- Abnormalities in liver function
- Jaundice
- Change in blood fats (lipids or cholesterol)
- 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

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- Decrease in number of white blood cells
- When men with prostate cancer first start treatment with PROSTAP 6, 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 PROSTAP 6 injection. If you do get worsening pain, weakness or loss of feeling in your legs or difficulty passing urine, contact your doctor immediately.
- Changes in ECG (electrocardiogram QT prolongation)
- Seizure
- Paralysis
- 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).
- 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 "bull's-eye" with a dark red centre surrounded by paler red rings (Erythema Multiforme).

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to 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 PROSTAP 6

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.

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 6 contains:

The active substance in PROSTAP 6 Powder is leuprorelin acetate (30 mg).

The other ingredients in PROSTAP 6 are: poly (D, L-lactic acid), which controls the release of the active ingredient into the body, and mannitol (E421).

The Sterile Solvent contains carmellose sodium, mannitol (E421), polysorbate 80, water for injections and acetic acid, glacial.

What PROSTAP 6 looks like and contents of the pack:

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PROSTAP 6 is a prolonged release powder for use in an injection.
The Sterile Solvent is a colourless liquid, which is mixed with the PROSTAP 6 Powder before injection.

Each pack contains a pre-filled dual chamber syringe containing 30 mg of leuprorelin acetate in the front chamber and 1 ml of Sterile Solvent in the rear chamber.

Marketing Authorisation Holder:

Takeda Products Ireland Ltd.

6th Floor,
South Bank House,
Barrow Street,
Dublin 4,
Ireland

Manufacturer:

Delpharm Novara S.r.l.
Via Crosa 86
28065 Cerano
Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Takeda Products Ireland Ltd,
5 Riverwalk,
Citywest Business Campus,
Dublin 24,
Ireland

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 6.

This leaflet was last revised in June 2024.

[Takeda logo]

This leaflet can be made available in large print, audio or Braille on request. Contact 0800 198 5000 to request this, quoting the following number: 2229/009/002
