Package Leaflet: Information for the user

PROSTAP® SR DCS

3.75 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 or your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you or your child 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 SR IS AND WHAT IT IS USED FOR

PROSTAP SR is a synthetic hormone which can be used to reduce the levels of testosterone and estrogen (sex steroids) circulating in the body.

Use in adults:

PROSTAP SR is 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 can also be used in women to reduce the thickness of the lining (endometrium) of the womb (uterus) in preparation for surgery and to treat endometriosis and uterine fibroids. PROSTAP SR can additionally be used to preserve ovarian function in pre-menopausal women with cancer who are having chemotherapy.

Use in children:

PROSTAP SR 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. Your doctor will make a precise diagnosis of central precocious puberty.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN PROSTAP SR

Do not use PROSTAP SR:

- If you are allergic (hypersensitive) to leuprorelin or any of the other ingredients of PROSTAP SR (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 pregnant, planning to become pregnant or are breastfeeding.
- If you have abnormal vaginal bleeding which you have not discussed with your doctor (see Warnings and Precautions section below).
- In pre and perimenopausal women receiving PROSTAP SR for the treatment of breast cancer:
    - your estrogen levels must have been adequately suppressed with PROSTAP SR before you start treatment with an aromatase inhibitor such as exemestane and should be checked every three months during combination treatment with PROSTAP SR 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 Precautions section below).

Warnings and precautions:

When you or your child begin treatment with PROSTAP SR, 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 SR (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 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 SR:

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 PROSTAP SR. 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 PROSTAP SR, 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.
- If you have a fatty liver.

Both men and women:

- PROSTAP SR may cause changes in blood pressure, blood fats (lipids or cholesterol) or blood glucose levels, similar to that seen when sex steroid levels naturally decrease (e.g. in women post menopause).
    - Your doctor may monitor you during treatment, as these changes may increase the risk of developing heart problems or changes in blood sugar control.
    - You should tell your doctor before receiving PROSTAP SR, as you may need more frequent monitoring, if you have:
        - Heart problems.
        - Diabetes.
- If you have diabetes, tell your doctor. PROSTAP SR can cause changes in blood glucose levels and your blood sugar levels may need to be monitored more frequently.
  If during treatment with PROSTAP SR 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 SR 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 SR 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 you are given PROSTAP SR. PROSTAP SR 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 have abnormal vaginal bleeding, tell your doctor before receiving PROSTAP SR. Your doctor should confirm why you are bleeding before you are given this medicine to make sure that it is suitable for you.
- If you are a woman with submucous fibroids (benign tumours in the muscle underneath the lining of the womb), PROSTAP SR can cause severe bleeding when the fibroids break-down. 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 SR, you should tell your doctor.
- If you are a woman of child-bearing age, you should use non-hormonal contraception whilst receiving PROSTAP SR. Although PROSTAP SR causes periods to stop, it is not itself a contraceptive. Once your treatment with PROSTAP SR has ended you should continue to use non-hormonal contraception until your periods start again. If you are unsure about this talk to your doctor.
- If you are being given PROSTAP SR for the treatment of breast cancer:

- Your doctor may assess your bone density and ovarian function before you start treatment with PROSTAP SR and monitor your bone density and ovarian function throughout treatment.
- PROSTAP SR 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, PROSTAP SR treatment should only commence once you have completed chemotherapy and pre-menopausal status has been confirmed.
- The recommended duration of treatment with PROSTAP SR in combination with other hormone treatments for breast cancer is up to 5 years.
- If you are being given PROSTAP SR 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 PROSTAP SR.
- If you are unsure about this, speak to your doctor.

Men only:

- In the rare event of an abscess occurring 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.
- 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 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 SR.

In children:

- In the event of a sterile abscess at the injection site (mostly reported after injection into the muscle) your doctor will monitor hormone levels as there could be reduced absorption of leuprorelin from the injection site.

- Often sterile abscesses at the injection site occurred when PROSTAP SR is administered in higher dosages than recommended and when it is administered into the muscle. Your doctor will therefore administer the medicinal product under the skin of e.g. abdomen, bottom or thigh.

- If a child has progressive brain tumour, the doctor will decide if treatment with leuprorelin is appropriate.

- Bone density may decrease during treatment of central precocious puberty with PROSTAP SR. 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.

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.**

- 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 PROSTAP SR

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

PROSTAP SR 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 SR must not be given to pregnant or breast-feeding women or girls (see also section “Do not use Prostap SR”).

Driving and using machines

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

PROSTAP SR 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 SR

PROSTAP SR 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 SR. The injection should be given immediately after it has been prepared. 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 a month.

If you are to be given PROSTAP SR to reduce the thickness of the lining of the womb (in preparation for surgery) you will receive a single injection 5-6 weeks before your surgery with treatment given during the first three to five days of the menstrual cycle.

If you have early breast cancer, you will be given PROSTAP SR once a month in combination with tamoxifen or an aromatase inhibitor. A minimum of two injections of PROSTAP SR 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 PROSTAP SR once a month as an add-on to your other breast cancer treatment.

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

If you have uterine fibroids you will be given an injection of PROSTAP SR once a month usually for 3-4 months before surgery.

If you are being given PROSTAP SR to preserve ovarian function whilst receiving chemotherapy, you will normally be given one injection of PROSTAP SR 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, 1 ml PROSTAP SR (3.75 mg leuprorelin acetate) is administered once a month under the skin of e.g. abdomen, bottom or thigh as a single 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, 0.5 ml PROSTAP SR (1.88 mg leuprorelin acetate) is administered once a month under the skin of e.g. abdomen, bottom or thigh as a single injection. The remainder of the suspension will 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.

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 PROSTAP SR 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 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 SR injection is missed, breakthrough bleeding or ovulation may occur with the potential for you to become pregnant. If you think you may be pregnant you should stop using PROSTAP SR and contact your doctor immediately.

If you stop using PROSTAP SR
If you are being given PROSTAP SR for the treatment of advanced or early breast cancer, you must not stop your treatment with PROSTAP SR whilst you are taking an aromatase inhibitor. If you are going to discontinue treatment with PROSTAP SR, your aromatase inhibitor treatment must also be discontinued within 1 month of your last PROSTAP SR injection.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PROSTAP SR 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:

- 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 SR. Although rare, these could be symptoms of changes in the number of red or white blood cells.

If any of the following side effects get serious, or if you notice any side effects not listed in this leaflet, speak to your doctor or pharmacist:

Men:

- When men with prostate cancer first start treatment with PROSTAP SR, 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 SR 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 PROSTAP SR, 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.

Very common (may affect more than 1 in 10 people)

Weight changes, hot flushes, sweating, muscle weakness, bone pain, loss of interest in sexual intercourse, inability to have an erection, a reduction in size and function of the testes, tiredness or skin reactions at the injection site (these include skin hardening, redness, pain, abscesses, swelling, nodules, ulcers and skin damage).

Common (may affect up to 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 or hands.

Uncommon (may affect up to 1 in 100 people)

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

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 which causes difficulty breathing or dizziness), changes in blood fats (lipids or 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, 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 "bulls-eye" with a dark red centre surrounded by paler red rings (Erythema Multiforme).

Women:

- When women first start treatment with PROSTAP SR, 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 PROSTAP SR 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, PROSTAP SR 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 PROSTAP SR, 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 sweating, swelling in ankles or hands 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)

Fatty liver, 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 or infection 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). 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)
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Side effects when used 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 GnRH analogues (Gonadotrophin 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)

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,
vaginal spotting,
vaginal discharge,
injection site reactions (these include hardening, redness, pain, abscesses, swelling, nodules, ulcers and skin damage)

Uncommon (may affect up to 1 in 100 people):

Fatty liver
Muscle ache

Very rare (may affect up to 1 in 10,000 people):

General allergic reactions (symptoms include fever, rash, itching, wheals or chills). If your child has , a serious allergic reaction causing difficulty breathing or dizziness, 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 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). 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 "bulls-eye" with a dark red centre surrounded by paler red rings (Erythema Multiforme).

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 pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PROSTAP SR

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 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 SR contains:

- The active ingredient in PROSTAP SR powder is leuprorelin acetate (3.75 mg).
- The other ingredients in PROSTAP SR are: gelatin, copoly (DL-lactic acid/glycolic 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 SR looks like and contents of the pack:

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

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

Each pack contains a pre-filled dual chamber syringe containing 3.75 mg leuprorelin acetate powder in the front chamber and 1 ml of Sterile Solvent in the rear chamber.

Marketing Authorisation Holder:

Takeda UK Limited
1 Kingdom Street,
London,
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Manufacturer:

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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 SR.

This leaflet was last revised in June 2025.

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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: 16189/0012