

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Decapeptyl® SR 3mg for Injection

Triptorelin

#### Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

1. What Decapeptyl SR is and what it is used for
2. Before you are given Decapeptyl SR
3. How Decapeptyl SR is given
4. Possible side effects
5. How to store Decapeptyl SR
6. Further Information

#### 1. What Decapeptyl SR is and What it is Used For

The active ingredient in Decapeptyl SR is triptorelin. Triptorelin belongs to a group of medicines called gonadotropin releasing hormone (GnRH) agonists. Triptorelin is similar to the gonadotropin releasing hormone which occurs naturally in your body. In men, triptorelin lowers the levels of the hormone testosterone. In women, it reduces oestrogen levels.

Decapeptyl SR is used in men and women to treat completely different conditions. Decapeptyl SR is available in two other strengths: Decapeptyl SR 11.25mg is used once every 3 months and Decapeptyl SR 22.5mg is used once every 6 months. Not all dose strengths are approved for all indications. Ask your doctor if you would like to discuss changing your treatment.

This leaflet gives information for the use of Decapeptyl SR in men and women. **Please read the column that is about you and your condition.**

Men	Women
<b>In men, Decapeptyl SR is used to treat prostate cancer.</b>	<b>In women, Decapeptyl SR is used to treat:</b> <ul style="list-style-type: none"><li>• <b>Endometriosis - a condition in which the tissue that normally lines the uterus (endometrium) grows in other places.</b></li><li>• <b>Uterine fibroids- abnormal (benign) growth of cells in your uterus.</b></li></ul>

#### 2. Before You Are Given Decapeptyl SR

Men	Women
<b>You should not be given Decapeptyl SR:</b> <ul style="list-style-type: none"><li>• if you know that you are allergic to triptorelin or similar types of drugs (other GnRH agonists) or any of the other ingredients. (Go to Section 6 'What Decapeptyl contains' for a list of the other ingredients.)</li></ul>	<b>You should not be given Decapeptyl SR:</b> <ul style="list-style-type: none"><li>• if you know that you are allergic to triptorelin or similar types of drugs (other GnRH agonists) or any of the other ingredients. (Go to Section 6 'What Decapeptyl contains' for a list of the other ingredients.)</li><li>• if you are pregnant or breast-feeding.</li></ul>

**Take special care with Decapeptyl SR:**

There have been reports of depression in patients taking Decapeptyl SR which may be severe. If you are taking Decapeptyl SR and develop depressed mood, **inform your doctor**.

If you are using medicines for preventing your blood clotting, you may experience bruising at the site of injection.

In adults if triptorelin or other GnRH agonists are used for a long period of time you may increase the risk of developing thin or weak bones, especially if you are a heavy drinker, a smoker, have a family history of osteoporosis (a condition that affects the strength of your bones), have a poor diet or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids). If you have anything wrong with you that affects your bones, such as osteoporosis, **tell your doctor**. This may affect the way your doctor decides to treat you.

When you first start treatment with Decapeptyl SR it actually **increases** the level of your hormones for a short time. This means that you may feel worse to begin with (see Section 4. 'Possible Side Effects' for more information). The doctor may give you some medicine (an anti-androgen) to prevent your symptoms from getting worse. After a short time the amount of hormone will drop and your symptoms will get better.

During the first weeks of treatment, Decapeptyl SR may, as with other GnRH agonists, in isolated cases, cause the spinal cord to compress or the urethra (where you pass urine) to block. You will be monitored by your doctor and given treatment for these conditions if they occur.

If you have diabetes, or if you suffer from heart problems, inform your doctor.

If you have an enlargement (benign tumour) of the pituitary gland that you were unaware of, this may be discovered during treatment with Decapeptyl SR. Symptoms include sudden headache, problems with eye sight and paralysis of the eye muscles.

**Tell your doctor** if you:

- notice blood in your urine or if you find it difficult or painful to urinate.
- Have back pain, weakness, numbness or tingling in your legs.

Your doctor may give you another drug to help you feel better during this time.

**Taking other medicines:**

Drugs which increase the level of a hormone called prolactin may react with Decapeptyl SR. Many different kinds of drugs may increase prolactin

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You may have some vaginal bleeding in the first month of treatment. After that your periods normally stop.

**Tell your doctor** if you have bleeding after the first month of treatment.

Your periods should start about 2 months after the last injection. **You must use some form of contraception other than the 'pill'** while you are having treatment and until you start your next period. Your doctor may suggest using a barrier method of contraception such as a condom or diaphragm (cap).

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**Driving and using machines:**

You may feel dizzy, tired or have problems with your sight such as blurred vision. These are possible side effects of treatment or from the underlying disease. If you experience any of these side effects you should not drive or use machines.

**Pregnancy and breast feeding:**

Do not take Decapeptyl SR if you are pregnant or breast feeding.

**Driving and using machines:**

You may feel dizzy, tired or have problems with your sight such as blurred vision. These are possible side effects of treatment or from the underlying disease. If you experience any of these side effects you should not drive or use machines.

**3. How Decapeptyl SR is Given**

**Men**

Decapeptyl SR 3mg will be injected into a muscle, usually your bottom, by a doctor or nurse.

On this leaflet there are instructions for them that explain how to prepare the injection.

You will normally receive an injection once every 28 days.

**Also read** 'Taking other medicines' in section 2.

**If you are given more Decapeptyl SR than you should:**

If you are given too much Decapeptyl SR you may experience additional or more severe side effects (see Section 4. 'Possible Side Effects').

**If you forget to take a dose of Decapeptyl SR :**

As soon as you realise that you have missed an injection you should **tell your doctor**. You will then be given your next injection.

**If you stop receiving Decapeptyl SR:**

If you stop receiving your Decapeptyl SR injection before your doctor tells you to then your symptoms are likely to return.

**If you have any further questions on the use of this product, ask your doctor or pharmacist.**

**Women**

Decapeptyl SR 3mg will be injected into a muscle, usually your bottom, by a doctor or nurse.

On this leaflet there are instructions for them that explain how to prepare the injection.

You will normally receive one injection every 28 days. This injection should be given in the first 5 days of your menstrual cycle.

If you are being treated for uterine fibroids you should be treated for at least 3 months.

You should not need to be treated for more than 6 months.

**Also read** 'Taking other medicines' in section 2.

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#### 4. Possible Side Effects

Men	Women
<p><b>Like all medicines, Decapeptyl SR can have side effects although not everybody gets them. In rare cases you may experience a severe allergic reaction. Tell your doctor immediately if you develop symptoms such as swallowing or breathing problems, a rash, swelling of your lips, face, throat or tongue.</b></p>	
<p>Many of the side effects are expected, due to the change in the level of testosterone in your body. These effects include hot flushes, impotence and decreased libido.</p> <p>Side effects which are <b>very common</b> (more than 1 in 10 patients treated) are hot flushes, weakness, excessive sweating, back pain, pins and needles sensation in the legs.</p> <p>At the beginning of treatment, increased bone pain, getting blood in your urine, back pain, weakness and numbness or tingling in your legs are common (see Section 2 “Take special care with Decapeptyl SR”).</p> <p>Side effects which are <b>common</b> (less than 1 in 10 patients treated) are nausea, tiredness, redness, bruising and/or pain at injection site, muscle and bone pain, pain in arms/legs, oedema (build-up of fluid in the body tissues), dizziness, headache, decreased sex drive, impotence, depression and mood changes.</p> <p>Side effects that are <b>uncommon</b> (less than 1 in 100 patients treated) are ringing in the ears, pain in abdomen, constipation, diarrhoea, vomiting, drowsiness, shaking, sleepiness, pain, some blood tests affected (including raised liver function tests), increase in weight, weight loss, gout (severe pain and swelling in the joints usually in the big toe), increase in appetite, joint pain, muscle cramp, muscle weakness, muscle pain, tingling or numbness, inability to sleep, irritability, development of enlarged breasts in men, breast pain, reduction in testicular size, pain in testicles, difficulty in breathing, acne, hair loss, itching, rash, high blood pressure.</p> <p>Side effects that are <b>rare</b> (less than 1 in 1000 patients treated) are red or purple discolorations on the skin, diabetes, vertigo, abnormal sensation in the eye, blurring or disturbance in vision, sensation of fullness in the abdomen, flatulence, dry mouth, abnormal sense of taste, chest pain, difficulty in standing, flu-like symptoms, fever, allergic reaction, anaphylactic reaction (serious allergic reaction which can cause dizziness or difficulty in breathing), inflammation of the nose/throat, increased body temperature, weight</p>	<p>At the beginning of treatment the symptoms of uterine fibroids and endometriosis (pelvic pain, painful periods) may be worse. These symptoms should disappear in one or two weeks.</p> <p>Many of the side effects are expected due to the change in the level of oestrogens in your body.</p> <p>Side effects which are <b>very common</b> (more than 1 in 10 patients treated) include headache, decreased libido, mood changes, difficulty in sleeping, pain during or after sexual intercourse, painful periods, vaginal bleeding, pelvic pain, vaginal dryness, excessive sweating and hot flushes.</p> <p>Side effects which are <b>common</b> (less than 1 in 10 patients treated) are breast pain, muscle cramps, painful joints, weight gain, feeling sick, depression, stomach pain or discomfort, redness or inflammation and/or pain at the injection site.</p> <p>Other reported side effects are: vomiting, diarrhoea, nose bleeds, general discomfort, increased blood pressure, muscle pain and weakness, anxiety, confusion, dizziness, absence of periods, swelling of your lips, face, throat and /or tongue, skin rash, difficulty in breathing, abnormal sensation in the eye and/or changes in sight.</p> <p>You may have some thinning or weakening of bone during treatment. This is thought to be reversible.</p> <p>Rarely, surgery for vaginal bleeding has been needed in patients treated for uterine fibroids.</p> <p>If you have uterine fibroids your doctor will check your response to treatment carefully. If you do not respond to treatment your doctor may do more tests.</p> <p><b>If any of the side effects become serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.</b></p>

loss, stiff joints, joint swelling, musculoskeletal stiffness, osteoarthritis, memory loss, feeling confused, decreased activity, having a feeling of elation or well-being, inability to ejaculate, shortness of breath when lying flat, blisters, nose bleeds, low blood pressure.

General discomfort has also been reported.

An increase in white blood cell count may be found, as with other GnRH analogues, in patients being treated with Decapeptyl SR.

**If any of the side effects become serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.**

## 5. How to Store Decapeptyl SR

Keep Decapeptyl SR out of the reach and sight of children.

Do not use the vial or ampoule after the expiry date printed on the box.

This medicinal product should not be stored above 25°C. The vial and ampoule should be kept in the outer box.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

## 6. Further Information

### What Decapeptyl SR contains:

The active substance of Decapeptyl SR is triptorelin. Each vial contains sufficient quantity of triptorelin (as triptorelin acetate) to ensure that the minimum triptorelin quantity injected is 3mg.

The other ingredients are d,l lactide-glycolide copolymer, mannitol, carmellose sodium, polysorbate 80.

### What Decapeptyl SR looks like and contents of the pack

Each pack contains:

- 1 clear glass vial with a rubber stopper and an aluminium cap containing the powder.
- 1 glass ampoule containing the suspension vehicle.
- 1 syringe
- 2 needles

### Marketing Authorisation Holder

Ipsen Limited, 190 Bath Road, Slough, Berkshire, SL1 3XE, UK.

### Manufacturer

Ipsen Pharma Biotech, Signes, France.

**Is this leaflet hard to see or read? Please phone 01753 627777 to ask for help.**

This leaflet was last revised in May 2012.

**Decapeptyl SR 3mg** PL 34926/0002

Suspension vehicle PL 34926/0008