**1.3.2 PATIENT INFORMATION LEAFLET**

## SCHEDULING STATUS

S4

## PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**SUPREFACT® 3-MONTH DEPOT** implant

(buserelin acetate)

**Read all of this leaflet carefully before you start taking SUPREFACT**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- SUPREFACT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## WHAT SUPREFACT CONTAINS

The active ingredient of SUPREFACT is called buserelin. Each pre-filled syringe (one implant) contains three identical rods each containing 3,3 mg buserelin acetate (9,9 mg), equivalent to 9,45 mg buserelin base. The total dose is gradually released over a 3-month period. The ingredient that controls the gradual release of buserelin from the rods is poly(D,L-lactide-co-glycolide) with a 75:25 ratio of lactide:glycolide.

Sugar free.

## WHAT SUPREFACT IS USED FOR

SUPREFACT contains a medicine called buserelin. Buserelin is similar to a natural hormone released by the brain. It belongs to a group of medicines called gonadotropin-releasing hormone (GnRH) analogues or luteinising hormone-releasing hormone (LHRH) analogues.

SUPREFACT works by lowering the amount of hormones which promote prostate tumour growth. The prostate is a gland that lies underneath the bladder of men. The suppressive effect is fully reversible.

SUPREFACT is used to treat advanced prostate cancer.

**BEFORE YOU RECEIVE SUPREFACT**

**You should not be given SUPREFACT:**

- If you are allergic to buserelin or any of the other ingredients of SUPREFACT. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- After surgical removal of the testes or after oestrogen (female hormone) therapy. Efficacy has not been established in these cases.

**Tell your doctor or healthcare professional before receiving SUPREFACT if:**

- You have high blood pressure. Your blood pressure must be checked regularly because SUPREFACT can affect you blood pressure control.
- You have diabetes. Check your blood sugar levels regularly, because SUPREFACT can affect your metabolism and therefore your blood sugar levels.
- You have ever had depression. There is a risk that your depression can return or get worse. Tell your doctor if you develop a depressed mood while being treated with SUPREFACT.
- You have metabolic bone disease or have additional risk factors for osteoporosis (a disease which causes bones to become less dense, gradually making them weaker, more brittle and likely to break); such as chronic alcohol abuse, smoking, a family history of osteoporosis or are on long-term therapy with anticonvulsants (medicines used to treat epilepsy or fits) or corticosteroids (such as prednisone, cortisone). Treatment with SUPREFACT can decrease bone density and your doctor will monitor your bone density and recommend preventative measures (see POSSIBLE SIDE EFFECTS).
- Your cancer has spread (metastatic cancer). It is recommended to use another medicine (called an anti-androgen) to lower certain hormones before and in parallel with SUPREFACT

treatment for the first 3 to 4 weeks. This additional therapy will reduce complications due to the temporary increase of testosterone levels at the beginning of treatment with SUPREFACT (see HOW TO RECEIVE SUPREFACT and POSSIBLE SIDE EFFECTS).

- If you have a decrease in the number of red blood cells (anaemia) or experience increased tiredness. Symptoms of anaemia include: tiredness, lack of energy, shortness of breath and palpitations.
- If you have any heart conditions, including heart rhythm problems (dysrhythmia), or are being treated with medicines for these conditions. The risk of heart problems may be increased with SUPREFACT treatment (see Using other medicines with SUPREFACT and POSSIBLE SIDE EFFECTS.

If you are unsure if any of the above apply to you, talk to your healthcare professional before your doctor implant SUPREFACT.

**Driving and using machinery**

You may experience side effects after receiving SUPREFACT. Some of these side effects (such as dizziness) can affect you being able to concentrate and your reaction speed. If this happens, be careful while driving, using any tools or machines or during any work that requires a high level of attention (see POSSIBLE SIDE EFFECTS).

**Using other medicines with SUPREFACT:**

Always tell your healthcare professional if you are using any other medicine. This includes complementary or traditional medicines.

In particular, tell your doctor if you are taking the following medicines:

- Medicines for diabetes. SUPREFACT can affect the way these medicines work, which can lead to worsening of your diabetes.
- Medicines to treat heart rhythm problems (antidysrhythmics such as quinidine, disopyramide, amiodarone, sotalol, procainamide, dofetilide, ibutilide).

- Other medicines that might increase the risk of heart rhythm problems (prolongation of the QT interval), such as methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic) and antipsychotics (used for mental illnesses) (see Tell your doctor or healthcare professional before receiving SUPREFACT if).

**HOW TO RECEIVE SUPREFACT**

You will not be expected to inject the SUPREFACT implant yourself. It will be injected by a person who is qualified to do so.

The site of the injection will be cleaned. A local anaesthetic may then be given to ease the pain of the implant injection.

The content of one pre-filled syringe (implant containing 3 rods to give a dose of 9,45 mg of buserelin) is injected under the skin (subcutaneous) in the stomach area, every 3 months. It is very important to maintain a regular 3-month interval between injections to maintain continuous suppression of testosterone. The 3-month interval may occasionally be extended by up to 3 weeks. Follow your doctor's advice on when you should receive SUPREFACT and the time between injections.

The doctor may decide to start anti-androgen treatment approximately 5 days before starting treatment with SUPREFACT and to continue parallel treatment for a period of 3 – 4 weeks (see Tell your doctor or healthcare professional before receiving SUPREFACT if, and POSSIBLE SIDE EFFECTS), especially in patients with metastases. The parallel treatment will reduce complications due to the passing increase in testosterone levels at the beginning of treatment. Your doctor will do blood tests to monitor blood levels.

**If you receive more SUPREFACT than you should:**

It is unlikely that your healthcare professional will give you too much SUPREFACT. Receiving too much SUPREFACT can make you feel weak, nervous, dizzy or sick (nauseous). You may also experience headaches, hot flushes, stomach pain, swelling (oedema) of the ankles and lower legs

and pain in your breasts. Local reactions at the injection site such as pain, bleeding and soreness may occur. Your doctor may give you appropriate treatment for these side effects.

**If you missed a scheduled implant of SUPREFACT:**

It is very important to adhere to the treatment regimen recommended by your doctor to maintain continuous suppression of testosterone. Talk to your doctor as soon as possible to determine the best way forward.

**Effects when treatment with SUPREFACT is stopped:**

The suppressive effect of SUPREFACT on testosterone levels and tumour growth will reduce.

**POSSIBLE SIDE EFFECTS**

SUPREFACT can have side effects.

If you experience a severe allergic reaction such as shortness of breath or swelling of the lips, face, throat or tongue, please contact your doctor immediately as it may become necessary to have your implant removed.

Not all side effects reported for SUPREFACT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you experience any side effect it is important that you inform your doctor before your next treatment.

**Side effects that may occur at the start of your treatment:**

At the beginning of treatment the amount of sex hormones that your body produces may increase and you may notice a temporary worsening of symptoms. For example, you may suffer from bone pain, muscle weakness in the legs, trouble in passing urine, fluid retention or blood clotting disorders in the lungs. Contact your doctor immediately if you experience shortness of breath or chest pain.

Usually you will be given another medicine (an anti-androgen) to reduce these symptoms (See Tell your doctor or healthcare professional before receiving SUPREFACT if, and HOW TO RECEIVE SUPREFACT).

However, even with concomitant anti-androgen therapy, the following side effects may occur:

- Temporary increase in tumour pain
- Deterioration of general well-being.

Tell your doctor as soon as possible if you experience any of the following side effects that may need medical attention and treatment:

- Allergic reactions such as skin rash which may be red and itchy (including urticaria)
- Increased thirst, changes in appetite, lowering of your glucose tolerance levels (in diabetic patients it may lead to a loss of diabetic control)
- Feeling nervous, stressed or emotionally unstable. Depression may develop, return or worsen during therapy with SUPREFACT
- Fast or uneven heartbeats (palpitations), rise in blood pressure in people who already have high blood pressure (hypertension)
- Build-up of fluid (oedema) around your ankles and the lower parts of your legs
- You feel very tired or notice bruising. This could be due to a decrease in the number of blood cells
- Discomfort or pain in the muscles or skeletal system. SUPREFACT may decrease bone density, which may lead to osteoporosis and an increased risk of bone fractures. The risk of bone fractures increases with the length of treatment.

Tell your doctor if you notice any of the following:

- Hot flushes
- Shrinking of your testicles (testicular atrophy)
- Inability to sustain an erection
- Loss of sexual drive (libido)

- Enlargement of your breasts (usually painless)
- Change in the amount of hair on your body or head
- An increase in the enzymes produced in your liver, as seen in the results of some blood tests
- Changes in blood lipids and increase in bilirubin, as seen in the results of some blood tests
- Weight change (increase or decrease)
- Headaches
- Feeling dizzy
- Difficulty sleeping and memory or concentration problems
- Feeling drowsy
- Ringing in your ear (tinnitus), changes in your hearing
- Changes to your eyesight such as blurred vision and a feeling of pressure behind your eyes
- Feeling sick (nauseous), being sick (vomiting) or diarrhoea
- Constipation
- Pain or other local reactions at the injection site (such as reddening or swelling)
- Feeling tired.

If you notice any side effects not mentioned in this leaflet, please tell your doctor or healthcare professional.

## STORING AND DISPOSING OF SUPREFACT

**Store all medicines out of reach of children.**

The sealed syringe must be stored at or below 25 °C in the original container. Only remove the syringe from the foil bag directly before use. Do not use after the expiry date stated on the pack. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## PRESENTATION OF SUPREFACT

A carton containing a sterile, plastic, disposable syringe, sealed in a foil bag.

## IDENTIFICATION OF SUPREFACT

Each implant contains three identical creamy-coloured rods in a disposable syringe.

## REGISTRATION NUMBERS

32/21.10/0345

## NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

Pharmaco Distribution (Pty) Ltd

3 Sandown Valley Crescent

South Tower, First Floor

Sandton 2196

Gauteng

South Africa

Ethical assistance Line: +27 (0) 784 00 77

## DATE OF PUBLICATION

Date registered: 03 June 1999

Date revised: 06 June 2018