

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Suprefact®

100 micrograms/metered dose Nasal Spray, solution

Buserelin (as Buserelin acetate)

SANOFI 



 **Is this leaflet hard
to see or read?
Phone 01 403 5600
for help**

**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.

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- 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

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

1. What Suprefact Nasal Spray is and what it is used for

Suprefact Nasal Spray contains a medicine called buserelin acetate. This belongs to a group of medicines called gonadotropin releasing hormone analogues. This is a synthetic version of a hormone that occurs naturally in the body. It works by lowering the production of sex hormones. It is used to treat prostate cancer by lowering the amount of the hormone 'testosterone'.

2. What you need to know before you use Suprefact Nasal Spray

Do not use this medicine and tell your doctor if:

- × You are allergic (hypersensitive) to:
 - buserelin
 - other similar medicines such as goserelin
 - any of the other ingredients of Suprefact Nasal Spray (listed in Section 6 below)

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- × You have a tumour that is not affected by changes in hormone levels
- × You have had an operation to remove your testicles

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Suprefact Nasal Spray.

Warnings and Precautions

Check with your doctor or pharmacist before using your medicine if:

- You have depression. There have been reports of depression in patients taking Suprefact Nasal Spray which may be severe. If you are taking Suprefact Nasal Spray and develop depressed mood, inform your doctor.
- You have high blood pressure. Your blood pressure must be checked regularly.
- You have or have had heart problems.
- You have diabetes. You should check your blood glucose levels regularly
- You have a metabolic bone disease or have additional risk factors for osteoporosis such as chronic alcohol abuse, smoking, a family history of osteoporosis or are on long-term therapy with medication for seizures or corticosteroids.
- You should also be taking medication that regulate your sex hormone levels (called anti-androgen e.g. cyptroterone acetate), if you are a male patient.

Studies suggest a relationship between gonadotropin-releasing hormone (GnRH) agonist treatment and increased risk of cardiovascular disease and diabetes mellitus. These risks should be evaluated before initiating and during therapy, and patients should be monitored and treated accordingly.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Suprefact Nasal Spray.

- Please tell your doctor if you have any of the following: 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 Suprefact Nasal Spray.

Other medicines and Suprefact Nasal Spray

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Suprefact Nasal Spray can affect the way some other medicines work. Also some medicines can affect the way Suprefact Nasal Spray works.

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

- medicines for diabetes

Suprefact Nasal Spray 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, breast-feeding and fertility

This medicine is intended for use in men.

Driving and using machines

You may feel dizzy, drowsy or have blurred eyesight while using this medicine. If this happens, do not drive or use any tools or machines.

Suprefact Nasal Spray contains

• Benzalkonium chloride

Suprecur Nasal Spray contains benzalkonium chloride. This may cause difficulty breathing, wheezing or tightness in the chest (bronchospasm).

• Sodium

This medicinal product contains less than 1 mmol (23mg) sodium per dose, i.e. essentially 'sodium-free'.

3. How to use Suprefact Nasal Spray

Always use Suprefact Nasal Spray exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Using this medicine

- Your doctor will normally give you Suprefact injection for seven days. The doctor will then start you on the nasal spray on the 8th day of your treatment.
- It is very important you use this medicine regularly and space the doses out evenly through the day
- This medicine can be used if you have a cold. If you have a cold, blow your nose thoroughly before using the spray. If you are using a nasal decongestant wait at least 30 minutes after using Suprefact Nasal Spray before using the decongestant.



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- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor
- Your doctor will monitor your hormone levels by taking regular blood samples.

How to use Suprefact Nasal Spray:

1. Preparing the spray

- Remove the screw cap from bottle
- Remove the metered-dose nebuliser from transparent plastic container and take off both protective caps
- Screw the nebuliser on to the bottle

2. If you are using the spray for the first time

- Hold the bottle upright
- Pump 5 to 8 times until an even spray is produced. This initial pumping is for the purpose of filling the system and testing the spray. It should not be repeated after the first use in order to avoid wasting the medicine

3. Using the spray

- Keep the bottle upright
- Bend your head slightly over the bottle
- Spray the solution into the nose

4. After using the spray

- After use leave the nebuliser on the bottle
- After replacing the protective cap on the nebuliser, the spray bottle is best stored in its transparent container in an upright position

How much Suprefact Nasal Spray to use: Treatment of Prostate Cancer:

- The usual dose is one spray in each nostril six times each day.
- Use the spray:
- In the morning – before and after breakfast
- At midday – before and after lunch
- In the evening – before and after dinner
- Your doctor will tell you how long to continue using this medicine

If you use more Suprefact Nasal Spray than you should

If you use more Suprefact Nasal Spray than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have used.

The following effects may occur: feeling weak, headache, feeling nervous, hot flushes, feeling dizzy, feeling sick, stomach pain, swelling of the legs and breast pain.

If you forget to use Suprefact Nasal Spray

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop using Suprefact Nasal Spray.

Keep using Suprefact Nasal Spray until your doctor tells you to stop. If you stop, your prostate cancer may get worse.

Blood Tests

Using Suprefact Nasal Spray may affect the results of some blood tests. In particular, Supre-

fact Nasal Spray can change the level of liver enzymes and fats in the blood (lipids) shown up in blood tests.

If you are going to have a blood test, it is important to tell your doctor you are using Suprefact Nasal Spray. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Stop using Suprefact and see a doctor or go to a hospital straight away if;

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have leg pain, difficulty breathing or being short of breath and chest pain. This could be because of blood clots in your body and lungs

Tell your doctor straight away if you notice any of the following serious side effects:

- You bruise more easily than usual. This could be because of a blood problem called ‘thrombocytopenia’
- You get a lot of infections. Signs include fever, sore throat or mouth ulcers. These could be signs of a blood problem called leucopenia
- You have nose bleeds and a hoarse voice.
- Changes in your sense of taste or smell
- You have severe headaches and eyesight problems. This is very rare but if it happens it could be due to tumours on the pituitary gland. This gland is found at the base of the brain.

- Your blood pressure becomes higher. This is very rare but if it happens you may get symptoms such as crushing chest pain, confusion, problems with your eyesight, tiredness and an uneven heartbeat
- You have problems passing water (urine)
- You have sharp pain or aching in your side in the area between the ribs and the hips. These could be signs of a swollen kidney
- You feel tired and your body is swollen. These could be signs of fluid build up in the tissues called lymphostasis
- You feel tired, lack energy; have shortness of breath and palpitations. These could be symptoms of anaemia, a decrease in the number of red blood cells. Due to testosterone suppression, GnRH agonist therapy may increase the risk of anaemia. Patients should be evaluated for this risk and managed accordingly.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Loss of sex drive (libido)
- Atrophy (shrinking) of the testes
- Bone or muscle discomfort such as shoulder pain or stiffness or muscle weakness. If Suprefact Nasal Spray is used for a long period of time, it may increase the risk of you getting a condition called ‘osteoporosis’. This is when your bones are more likely to break
- Lowered tolerance to glucose which may lead to worsening of existing diabetes
- Changes in body weight, changes in appetite and increased thirst
- Mood changes such as depression (feeling depressed) or worsening of depression: long

term use: common, short term use: uncommon and feeling anxious.

- Feeling nervous, dizzy, tired or drowsy
- Headache and disturbed sleep
- Problems with memory and concentration
- Dry eyes (possibly leading to eye irritation in people who wear contact lenses), blurred eyesight, feeling of pressure behind the eyes
- Hearing problems such as ringing in the ears (tinnitus)
- Very fast, uneven or forceful heartbeat (palpitations)
- Swollen arms or legs due to water retention
- Feeling or being sick, stomach ache, pain in the lower abdomen, diarrhoea or constipation
- Dry skin or acne or hot flushes
- Hair grows more than normal (including body and facial hair)
- Hair loss (including body or facial hair)
- Increase in breast size or breast tenderness
- Changes in the level of liver enzymes, fats (lipids) and a substance called ‘bilirubin’ in the blood shown up in blood tests.
- Frequency unknown: changes in ECG (QT prolongation)

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 Suprefact Nasal Spray

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Suprefact Nasal Spray after the expiry date (EXP) which is stated on the carton and bottle after ‘EXP’. The expiry date refers to the last day of that month.

Do not store your nasal spray above 25°C. Do not freeze. One bottle has enough solution to last one week. You should stop using a bottle at the end of one week after first opening and start a new bottle.

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

6. Contents of the pack and other information

What Suprefact Nasal Spray contains

- Each spray dose contains 100 micrograms of the active substance, buserelin as buserelin acetate
- The other ingredients are citric acid monohydrate, sodium citrate, sodium chloride, benzalkonium chloride and water for injections.

What Suprefact Nasal Spray looks like and contents of the pack

Suprefact Nasal Spray is available in boxes containing four bottles and four spray pumps. Each bottle contains 10 grams of solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
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Citywest Business Campus,
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Manufacturer

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Industriepark Höchst,
D-65926 Frankfurt am Main,
Germany

This package contains a metered dose nebuliser – CE0123

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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