

TITLE - BUSERELIN ACETATE / SUPREFACT MEDICATION PATIENT INFORMATION IN ENGLISH

Source : Medicines Org UK

Disclaimer : Document presented by www.911GlobalMeds.com



Express Medicine Shipments, Globally!

FOR PUBLIC INTEREST & INFORMATION ONLY.
NO BRAND OR GENERIC MEDICINE IS BEING PROMOTED
FOR SALES FROM THE CONTENT OF THIS DOCUMENT.

Suprefact® 1mg/ml Injection

Buserelin acetate

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

1. What Suprefact Injection is and what it is used for

Suprefact Injection contains a medicine called buserelin. 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 Injection

Before using Suprefact, your doctor should assess your risk of developing diseases of heart and blood vessels (cardiovascular disease), diabetes mellitus and anaemia. If you develop any of the above, you should be monitored and treated accordingly.

Do not use this medicine and tell your doctor if:

- X You are allergic (hypersensitive) to:
 - buserelin
 - other similar medicines such as goserelin
 - any of the other ingredients of Suprefact Injection (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
- X You have had an operation to remove your testicles
- X You have a tumour that is not affected by changes in hormone levels
- X This medicine is intended for men only. Another presentation is available for women. It is important that these medicines are not used during pregnancy or breast-feeding.

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 Injection.

Take special care with Suprefact Injection

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

- You have depression. There have been reports of depression in patients using Suprefact Injection which may be severe. If you are using Suprefact Injection and develop depressed mood, inform your doctor
- You have high blood pressure. Your blood pressure must be checked regularly
- You have diabetes. You should check your blood glucose levels regularly
- You have 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 anticonvulsants or corticosteroids

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

Warnings and precautions

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 Injection.

Other medicines and Suprefact Injection

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 Injection can affect the way some other medicines work. Also some medicines can affect the way Suprefact Injection works.

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

- medicines for diabetes

Suprefact Injection 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 breast-feeding

This medicine is intended for use in men. However, there is another type of this medicine which can be used in women. Women should not use either type of this medicine if they are pregnant or breast feeding.

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.

Important information about some of the ingredients of Suprefact Injection

Suprefact injection contains:

- Benzyl alcohol. It must not be given to premature or newborn babies. Benzyl alcohol may cause toxic reactions and allergic reactions in infants and children up to 3 years old.

3. How to use Suprefact Injection

Suprefact Injection is normally given by a doctor or nurse. This is because it needs to be given as an injection underneath the skin (subcutaneous injection).

How much Suprefact Injection is given

If you are not sure why you are being given Suprefact Injection or have any questions about how much Suprefact Injection is being given to you, speak to your doctor or nurse.

- 0.5ml of Suprefact Injection will be given to you every 8 hours for 7 days
- After 7 days of treatment, you will be given the nasal spray

If you have more Suprefact Injection than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will monitor your progress by testing your blood at regular intervals and check the medicine you are given. Always ask if you are not sure why you are getting a dose of medicine.

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. You may also have pain, bleeding or hardening of the skin at the site of injection.

If you miss a dose of Suprefact Injection

Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you do think you have missed a dose, tell your doctor or nurse.

If you are injecting this medicine yourself and 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 having Suprefact Injection.

Keep using Suprefact Injection until your doctor tells you to stop. This is important in helping treat your tumour.

Blood Tests

Using Suprefact Injection may affect the results of some blood tests. In particular, Suprefact Injection 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 Injection.

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 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

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 Injection 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 feeling depressed or worsening of depression and feeling anxious.
Mood changes, depression
Frequency: Long term use: common
Short term use: Uncommon
- Feeling nervous, dizzy, tired or drowsy
- Headache and disturbed sleep
- Problems with memory and concentration
- Pain or redness at the injection site
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin. This can feel like 'pins and needles' (usually in the arms and legs) and is called paraesthesia
- 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)
- Facial swelling (puffiness) due to water retention which may also cause swollen arms or legs
- 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)
- Splitting of nails
- 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 not known: 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 the Yellow Card Scheme at: 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 Suprefact Injection

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

Do not use Suprefact Injection after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month. Once opened use within 15 days.

Do not store above 25°C. Do not freeze.

Keep the vials in the outer carton in order to protect from light.

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 Injection contains

Each 1 ml contains 1 milligram of the active substance, buserelin as buserelin acetate

The other ingredients are, sodium chloride, sodium dihydrogen phosphate, sodium hydroxide, benzyl alcohol and water for injections

What Suprefact Injection looks like and contents of the pack

Suprefact Injection is available in boxes containing two multidose vials. Each vial contains 5.5 milligrams of solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Neon Healthcare Ltd., Mill Studio Business Centre, Crane Mead, Ware,
Hertfordshire, SG12 9PY, UK

Manufacturer

Sanofi-Aventis Deutschland GmbH
Industriepark Höchst,
65926 Frankfurt am Main,
Germany

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.

This leaflet was last revised in October 2020