

PACKAGE LEAFLET: INFORMATION FOR THE USER

Suprefact® 1 mg/ml Injection

solution for 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you 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 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 Injection, 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 Suprefact Injection:

- if you are allergic to buserelin acetate, any of the other similar medicines such as goserelin or any of the other ingredients of this medicine (listed in section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you have had an operation to remove your testicles.
- if you have a tumour that is not affected by changes in hormone levels.
- 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 this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Suprefact Injection.

Warnings and precautions

Talk to your doctor before using Suprefact Injection.

Especially take care with Suprefact Injection and check with your doctor or pharmacist before using this 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.
- if you have high blood pressure. Your blood pressure must be checked regularly.
- if you have diabetes. You should check your blood glucose levels regularly.
- if 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 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 Suprefact Injection.

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

Other medicines and Suprefact Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- medicines for diabetes
- medicines for heart rhythm problems:
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.

Suprefact Injection contains benzyl alcohol

This medicine contains 5 mg benzyl alcohol in each dosage unit (0,5 ml) which is equivalent to 10 mg/ml solution.

Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gaspings syndrome") in young children.

Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

3. How to use Suprefact Injection

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Posology

- 0.5 ml 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.

Method of administration

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).

The doctor or nurse will usually give you the first injections. You may then be trained how to give the injections to yourself. Your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately.

If you use 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.

If you give yourself more Suprefact Injection 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 taken.

The following effects may occur when using too much Suprefact Injection: 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 forget to use 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 using 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, this medicine 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.
- if 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.
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, 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 Suprefact Injection

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Do not throw away any 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 Suprefact Injection contains

- The active substance is buserelin as buserelin acetate.
Each 1 ml of solution contains 1 mg of buserelin, equivalent to 1,05 mg buserelin acetate.

- The other ingredients are sodium chloride, sodium dihydrogen phosphate, sodium hydroxide, benzyl alcohol and water for injection.

What Suprefact Injection looks like and contents of the pack

Suprefact Injection is a clear, colourless, sterile solution.

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Neon Healthcare Ltd.
8 The Chase, John Tate Road,
Hertford,
SG13 7NN
United Kingdom

Manufacturer

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

or

Laboratorios Farmalan S.A.
Calle La Vallina S/n, Poligono Industrial Navatejera
Villaquilambre, 24193 León
Spain

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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