

**PACKAGE LEAFLET:
INFORMATION FOR THE USER****Suprecur®
150 micrograms/metered dose
Nasal Spray, solution***Buserelin (as Buserelin acetate)*SANOFI  **Is this leaflet hard
to see or read?
Phone 01 4035600
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.
- 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.



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What is in this leaflet

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

**1. What Suprecur Nasal Spray is
and what it is used for**

The name of your medicine is Suprecur 150 micrograms/metered dose Nasal Spray, solution (called Suprecur Nasal Spray throughout this leaflet). It 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 can be used for the following:

- Treatment of endometriosis – an illness where some of the tissues that line the womb are found elsewhere in the body
- As part of a treatment for infertility – it works by stopping the natural production of hormones that control ovulation. Synthetic hormones are then used to artificially stimulate ovulation. Your doctor should give you more information about how your treatment works

**2. What you need to know before you use
Suprecur Nasal Spray** **Do not use this medicine and tell your doctor if:**

- × You are allergic (hypersensitive) to buserelin or other similar medicines such as goserelin, benzalkonium chloride or any of the other ingredients of Suprecur 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 abnormal menstrual bleeding where the cause is not endometriosis
 - × You have a tumour that is affected by hormones
 - × You are pregnant or breast-feeding
- This medicine is for use in women only. Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Suprecur 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 Suprecur Nasal Spray which may be severe. If you are taking Suprecur Nasal Spray and develop depressed mood, inform your doctor
 - ▲ You have high blood pressure. Your blood pressure must be checked regularly
 - ▲ You have diabetes. Your blood glucose levels must be checked regularly
 - ▲ You have endometriosis and are taking oral contraceptives (the Pill or mini Pill). Your doctor will ask you to change to another form of contraception
 - ▲ 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 medication for seizures or corticosteroids.
 - ▲ You have polycystic ovarian disease
- If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before having Suprecur 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 Suprecur Nasal Spray.

**Other medicines and Suprecur 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 Suprecur Nasal Spray can affect the way some other medicines work. Also some medicines can affect the way Suprecur Nasal Spray works.

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

- Medicines for diabetes
 - Oral contraceptives (the Pill or mini Pill). If you have endometriosis and are taking oral contraceptives your doctor will ask you to change to another form of contraception
- Suprecur 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

Do not use this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant. This is because Suprecur Nasal Spray may be harmful to the developing baby. Women must have a pregnancy test to make sure they are not pregnant before starting this medicine. Suprecur Nasal Spray will be stopped before you are given the hormones used to stimulate ovulation
- You are breast-feeding or planning to breast-feed. This is because small amounts may pass into mothers' milk

Women with endometriosis should use non-hormonal methods of contraception (such as condoms). This is to prevent pregnancy during treatment with this medicine. If treatment is interrupted even for only a few days, ovulation may occur and there is a risk of pregnancy. If you get pregnant during treatment, stop using this medicine and tell your doctor immediately. Ask your doctor or pharmacist for advice before taking any medicine if you 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.

Suprecur Nasal Spray contains

Suprecur Nasal Spray contains benzalkonium chloride. This may cause difficulty breathing, wheezing or tightness in the chest (bronchospasm). This medicinal product contains less than 1 mmol of sodium (23mg) per dose, i.e. essentially 'sodium-free'.

3. How to use Suprecur Nasal Spray

Always use Suprecur 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

- 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 Suprecur Nasal Spray before using the decongestant
- Do not use in children
- Do not use in women who have gone through the menopause (sometimes called 'the change of life')



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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.

How to use Suprecur 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 Suprecur Nasal Spray to use:
Treatment of endometriosis:**

- The usual dose is one spray in each nostril three times each day. This is to make a total daily dose of 900 micrograms
- Use the spray in the morning, at mid-day and in the evening
- Treatment will be for a maximum of 6 months

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- Treatment should be started on the first or second day of your menstrual period. This is to lower the chances you may be pregnant. Your doctor may perform a pregnancy test if there is any doubt
- You may get a menstrual period after the first few weeks of using this medicine. You may also carry on getting breakthrough bleeding or spotting

As part of treatment for infertility:

- The usual dose is one spray in one nostril only, four times each day to make a total daily dose of 600 micrograms
- Space the doses evenly throughout the day
- After you have been using this medicine for two to three weeks, you may be given other hormones to take as well as Suprecur Nasal Spray
- Your doctor will tell you how long to continue taking these medicines

Use in Children

This medicine should not be used in children.

If you use more Suprecur Nasal Spray than you should

If you use more Suprecur 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 Suprecur 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 Suprecur Nasal Spray

Keep using Suprecur Nasal Spray until your doctor tells you to stop. If you stop, your endometriosis may get worse or your infertility treatment may be affected.

Blood Tests

Using Suprecur Nasal Spray may affect the results of some blood tests. In particular, Suprecur 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 Suprecur 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, Suprecur Nasal Spray can cause side effects, although not everybody gets them.

Stop using Suprecur Nasal Spray 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 diarrhoea, pain, swelling or a feeling of tension in your stomach, feel sick or are sick, have gained weight, are having difficulty breathing or are short of breath or are passing less urine. These could be signs of a serious side effect called 'Ovarian Hyperstimulation Syndrome'. This is more likely if you are taking other hormones as well as Suprecur Nasal Spray (buserelin) as part of a treatment for infertility
- You are receiving In-vitro fertilisation/embryo transfer programs and similar assisted reproduction procedures carry inherent risks e.g. increased occurrence of ectopic pregnancies, miscarriages or multiple pregnancies; this also applies where buserelin is used as adjunctive therapy.

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

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

- Menopausal-like symptoms and bleeding
- Some weeks after starting treatment you may get signs such as hot flushes, increased sweating, dry vagina, painful sexual intercourse or loss of sex drive (libido). These may be severe in some cases. Breakthrough bleeding or spotting may also occur
- Pain, discomfort or swelling in the lower part of the stomach, changes to your periods, constipation, diarrhoea or needing the toilet more often. These symptoms could be a sign of ovarian cysts.
- Bone or muscle discomfort such as shoulder pain or stiffness. Bones may become less dense during long-term treatment, due to a lowering in the amount of bone mineral. This effect is reversible when treatment is stopped.

If Suprecur 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 (which may be like a migraine) and disturbed sleep
- Problems with memory and concentration
- 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
- Hair grows more than normal (including body and facial hair)
- Hair loss (including body or facial hair)
- Splitting of nails
- Vaginal discharge, changes in breast size, breast tenderness, hot flushes or milk production
- Changes in the level of liver enzymes, fats (lipids) and a substance called 'bilirubin' in the blood shown up in blood tests
- Worsening of your condition if you have uterine fibroids
- 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 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 Suprecur Nasal Spray

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

Do not use Suprecur 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 above 25°C. Do not freeze. Once opened the product should be used within 5 weeks. 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 Suprecur Nasal Spray contains

- Each spray dose contains 150 micrograms of the active substance, buserelin as buserelin acetate
- The other ingredients are citric acid monohydrate, sodium citrate, sodium chloride and benzalkonium chloride and water for injections.

What Suprecur Nasal Spray looks like and contents of the pack

Suprecur Nasal Spray is available in a carton containing one bottle with 10g of solution and also contains a metered-dose pump (nebuliser).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
sanofi-aventis Ireland Ltd., T/A SANOFI
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Manufacturer

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

This package contains a metered dose nebuliser – CE0123

Manufacturer: Sanofi-Aventis Deutschland GmbH,
D-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.

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