

- 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 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 Suprecur Injection

This medicine should be kept in a safe place where children cannot see or reach it.

Do not use Suprecur Injection after the expiry date which is stated on the carton and label. 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.

Discoloured or cloudy solution should not be used.

Each vial contains enough solution for ten doses. After finishing a course of treatment the vial should be disposed of and a new vial started for the next treatment.

Medicines should not be disposed of via wastewater or household waste. If you are using this medicine at home you will be given a container (a sharps bin) to use for disposal. Return the sharps bin or any used or unused syringes to your doctor or nurse or pharmacist for disposal. These measures will help to protect the environment.

### 6. Contents of the pack and other information

#### What Suprecur Injection contains

- Each 1ml of solution 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 Suprecur Injection looks like and contents of the pack

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

#### Marketing Authorisation Holder and Manufacturer

##### Marketing Authorisation Holder

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##### 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 July 2019**

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### PACKAGE LEAFLET: INFORMATION FOR THE USER

# Suprecur® 1mg/ml Injection

Buserelin acetate

SANOFI 

 **Is this leaflet hard to see or read?  
Phone 0845 372 7101 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.

### What is in this leaflet

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

### 1. What Suprecur Injection is and what it is used for



The name of your medicine is Suprecur 1mg/ml Injection (called Suprecur Injection 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 to treat 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 Injection

#### Do not have this medicine and tell your doctor if:

- × You are allergic (hypersensitive) to buserelin or other similar medicines such as goserelin, or any of the other ingredients of Suprecur 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
- × You have abnormal menstrual bleeding
- × You are pregnant or breast-feeding
- × You have a tumour that is not affected by changes in hormone levels
- × This medicine is for use in women only. However there is another form of this medicine that can be used in men. Men should not use either form of this medicine if they have had their testicles removed

Do not have this medicine if any of the above apply to you. If you are not sure, talk to your doctor or nurse before having Suprecur Injection.

#### Take special care with Suprecur Injection

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

- ▲ You have depression. There have been reports of depression in patients using Suprecur Injection which may be severe. If you are using Suprecur 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
- ▲ 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 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 Suprecur Injection.



#### Other medicines and Suprecur 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 Suprecur Injection can affect the way some other medicines work. Also some medicines can affect the way Suprecur Injection works.

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

- medicines for diabetes

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Suprecur 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

Do not have this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant. This is because Suprecur Injection may be harmful to the developing baby. Women must have a pregnancy test to make sure they are not pregnant before being given this medicine. Suprecur Injection 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

If you get pregnant during treatment, stop having 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 having this medicine. If this happens, do not drive or use any tools or machines.

#### Important information about some of the ingredients of Suprecur Injection

Suprecur 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 Suprecur Injection is given

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

#### Using this medicine

- 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.

#### How much Suprecur Injection is given

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

Your doctor will start treatment on day 1 or day 21 of your menstrual cycle. Your daily dose will be:

- 200 to 500 micrograms given as a single daily injection or 500 micrograms twice a day
- You will be given daily injections until blood tests show that levels of sex hormones are lowered. This usually takes one to three weeks
- You will then be given other hormones as well as Suprecur Injection
- Your doctor will tell you how long you are to continue having these medicines

If you are able to give Suprecur Injection 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 have more Suprecur 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, 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 Suprecur 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.

Having too much Suprecur Injection may make you feel weak, nervous, dizzy and sick. You may also have a headache, hot flushes, 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 Suprecur 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 Suprecur Injection.

Keep using Suprecur Injection until your doctor tells you to stop. If you stop, your infertility treatment may be affected.

#### Blood Tests

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



#### Stop having Suprecur 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 may also have pain or a skin rash in the area you were injected with Suprecur
- 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 Injection (buserelin) as part of a treatment for infertility

#### 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

#### 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 withdrawal 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 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 (which may be like a migraine) and disturbed sleep

Turn Over

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