

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Buserelin 1 mg/ml 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 Buserelin Injection is and what it is used for
2. What you need to know before you use Buserelin Injection
3. How to use Buserelin Injection
4. Possible side effects
5. How to store Buserelin Injection
6. Contents of the pack and other information

**1. What Buserelin Injection is and what it is used for**

The name of your medicine is Buserelin Injection. It 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 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 Buserelin Injection**

**Do not use Buserelin Injection:**

- if you are allergic to buserelin acetate or any 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 abnormal menstrual bleeding.
- if you are pregnant or breast-feeding.
- 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 Buserelin Injection.

### **Warnings and precautions**

Talk to your doctor before using Buserelin Injection.

Especially take care with Buserelin 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 Buserelin Injection which may be severe. If you are using Buserelin 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 polycystic ovarian disease.
- 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 Buserelin Injection.

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

### **Other medicines and Buserelin 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.  
Buserelin 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**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not have this medicine:

- if you are pregnant, might become pregnant or think you may be pregnant.

This is because Buserelin 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. Buserelin Injection will be stopped before you are given the hormones used to stimulate ovulation.

- if 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.

### **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.

### **Anti-doping information**

The use of the medicinal product may lead to positive results in doping tests. In addition, misuse as a doping agent may endanger health.

### **Buserelin Injection contains benzyl alcohol**

This medicine contains 2 - 5 mg benzyl alcohol in each dosage unit (depending on the applied dose) which is equivalent to 10 mg/ml solution.

Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

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").

### **Buserelin Injection contains sodium**

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

## **3. How to use Buserelin Injection**

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

### Posology

Your doctor will start treatment on day 1 or day 21 of your menstrual cycle.

The recommended daily dose is 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 Buserelin Injection. Your doctor will tell you how long you are to continue having these medicines.

#### Method of administration

Buserelin 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 Buserelin 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 Buserelin 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.

Using too much Buserelin 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 forget to use Buserelin 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 Buserelin Injection**

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

#### **Blood tests**

Using Buserelin Injection may affect the results of some blood tests. In particular, Buserelin 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 Buserelin 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 Buserelin Injection 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 Buserelin Injection.
- if 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 Buserelin 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 leukopenia.
- 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 Buserelin 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 (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 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, Website: [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 Buserelin 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 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.

Do not throw away any medicines 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 Buserelin 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 Buserelin Injection looks like and contents of the pack**

Buserelin Injection is a clear, colourless, sterile solution.

Buserelin Injection is available in packs containing two multidose vials. Each vial contains 5.5 ml 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,  
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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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