

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Buserelin 150 micrograms Nasal Spray Solution**  
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 Nasal Spray is and what it is used for
2. What you need to know before you use Buserelin Nasal Spray
3. How to use Buserelin Nasal Spray
4. Possible side effects
5. How to store Buserelin Nasal Spray
6. Contents of the pack and other information

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

The name of your medicine is Buserelin 150 micrograms Nasal Spray Solution (called Buserelin Nasal Spray throughout this leaflet). 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 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 Buserelin 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 Buserelin Nasal Spray (listed in section 6). 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 not affected by hormones.
- You are pregnant or breast-feeding.
- You are male. 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 use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Buserelin Nasal Spray.

**Take special care with Buserelin Nasal Spray**

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

- You have depression. There have been reports of depression in patients taking Buserelin Nasal Spray which may be severe. If you are taking Buserelin 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 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 using Buserelin Nasal Spray.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Buserelin 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 Buserelin Nasal Spray.

### **Other medicines and Buserelin Nasal Spray**

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 Buserelin Nasal Spray can affect the way some other medicines work. Also some medicines can affect the way Buserelin 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.

Buserelin 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 and breast-feeding**

Do not use this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant. This is because Buserelin 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. Buserelin 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' breast-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.

### **Buserelin Nasal Spray contains benzalkonium chloride.**

This medicine contains 0.1 mg benzalkonium chloride in each spray dose. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

## **3. How to use Buserelin Nasal Spray**

Always use this medicine exactly as your doctor has told you. 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 Buserelin Nasal Spray. If you are using a nasal decongestant wait at least 30 minutes after using Buserelin Nasal Spray before using the nasal decongestant.
- Do not use in children.
- Do not use in women who have gone through the menopause (sometimes called ‘the change of life’).
- 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 Buserelin Nasal Spray:**

#### **1. Preparing the spray**

- Remove the screw cap from bottle.
- Remove the metered-dose nebulizer from transparent plastic container and take off both protective caps.
- Screw the nebulizer 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 nebulizer on the bottle.
- After replacing the protective cap on the nebulizer, the spray bottle is best stored in its transparent container in an upright position.

### **How much Buserelin 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.
- 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 Buserelin 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 Buserelin Nasal Spray than you should**

If you use more Buserelin Nasal Spray than you should, tell your 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 Buserelin 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 Buserelin Nasal Spray**

Keep using Buserelin 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 Buserelin Nasal Spray may affect the results of some blood tests. In particular, Buserelin 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 Buserelin 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, this medicine can cause side effects, although not everybody gets them.

#### **Stop using Buserelin 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 Buserelin Nasal Spray (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 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 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 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 feeling depressed or worsening of depression and feeling anxious. Mood changes, depression
- Frequency:** Long term use: common (may affect up to 1 in 10 people); Short term use: Uncommon (may affect up to 1 in 100 people).
- 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, stomachache, 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
  - Changes in ECG (QT prolongation) **Frequency:** Not known

**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 Buserelin Nasal Spray**

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 bottle. The expiry date refers to the last day of that month.

Store between 2 °C and 25 °C. Do not freeze.

Once opened the product should be used within 5 weeks.

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 Buserelin Nasal Spray contains**

- Each spray dose contains 150 micrograms of the active substance, buserelin as buserelin acetate.
- The other ingredients are citric acid, sodium citrate, sodium chloride and benzalkonium chloride in aqueous solution.

### **What Buserelin Nasal Spray looks like and contents of the pack**

Buserelin Nasal Spray is available in carton containing two bottles and two metered-dose pumps (nebulisers). Each bottle contains 10 grams 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

This package contains a metered dose nebulizer.

### **CE**

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