

Package leaflet: Information for the user

Synarel®

200 micrograms / dose

Nasal Spray Solution

nafarelin



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

Important things that you SHOULD know about your medicine:

- Synarel is for the treatment of endometriosis, uterine fibroids, or as part of a supervised fertility programme and is for use by women only.
- You should use Synarel regularly as instructed by your doctor or nurse, in order for it to be effective.
- Most people do not have serious problems when using Synarel but side effects can occur – see Section 4 for details.
- Taking other medicines may sometimes cause problems. Check with your doctor or pharmacist before taking this or any other medicines.

Please read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important to you. If you have any further questions, ask your doctor or pharmacist.

1. What Synarel is and what it is used for

Synarel contains nafarelin and works by reducing the normal response of your body to a hormone called GnRH (gonadotrophin releasing hormone). As a result, your ovaries produce less of another hormone called oestrogen. You will notice the reduced amount of oestrogen usually by your periods either stopping or being reduced in amount after about one month of taking Synarel.

Synarel has to get into your blood stream before it can work. This cannot happen if it is taken by mouth, because your stomach acid will break it down and it will be digested. Therefore, nasal inhalation is a simple way to get this medicine into your blood stream.

Synarel is used to treat endometriosis, manage uterine fibroids and can also be prescribed with other medicines

for women trying to become pregnant as part of a supervised fertility programme.

2. What you need to know before you use Synarel

Do not use Synarel

- If you are allergic to nafarelin acetate or have had a reaction to gonadotrophin releasing hormone, similar drugs or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or may become pregnant whilst using Synarel. If you are using Synarel as part of a fertility programme, your pregnancy will be planned to take place after you stop using this medicine.
- If you suffer from vaginal bleeding, for which your doctor could not find the cause.
- If you are currently breast-feeding.
- If you have a hormone dependent tumour, or if you have had one in the past.

Warnings and precautions

Talk to your doctor or pharmacist before using Synarel

- If you suffer from Polycystic Ovarian Disease as there is a potential risk for excessive follicular stimulation.
- If you think you might be pregnant there is a risk to the development of the foetus and/or miscarriage.

Your doctor will advise whether you can still use Synarel.

Synarel is not recommended for use in women under 18 years of age.

Retreatment with Synarel or use for longer than 6 months due to possible effect on bone mineral density is therefore not recommended.

There have been reports of depression in patients taking Synarel which may be severe. If you are taking Synarel and develop depressed mood, inform your doctor.

Use of Synarel in combination with gonadotropin to treat infertility can sometimes cause an overreaction in your ovaries (ovarian hyperstimulation syndrome, OHSS). You may notice stomach pain, swelling of your stomach, and feeling or being sick. If this happens, tell your doctor. See also section 4 Possible side effects.

Tell your doctor if you are due to have any medical tests as the results may be affected.

Other medicines and Synarel

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Nasal decongestants should not be used within the 30 minute period before or after taking a dose of Synarel as they can reduce absorption of the medicine in the nose. If your nose is congested, Synarel will still be absorbed.

If you have been using an oral contraceptive to prevent pregnancy, your doctor will ask you to stop taking these and use a barrier method of contraception (diaphragm, condom) to stop you becoming pregnant.

You should always tell your doctor if you are taking or have recently taken any other medicine, even those not prescribed.

Synarel with food and drink

Please refer to section 3.

Pregnancy, breast-feeding and fertility

Do not use Synarel if you are pregnant or trying to become pregnant.

Do not use Synarel if you are breast-feeding.

Driving and using machines

Synarel is not known to affect the ability to drive or use machines.

Synarel contains benzalkonium chloride

Synarel contains 0.01 mg benzalkonium chloride in each spray. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How to use Synarel

How to use your medicine

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

Synarel is for administration by the intranasal route only. Synarel can be used with or without food.

If you sneeze while spraying Synarel, you will need to use another dose of Synarel.

For endometriosis: the usual dose is one spray twice each day for six months. Spray into one nostril in the morning, and the other nostril in the evening (a total of 2 sprays per day). You should use the spray for the first time between the second and fourth day of your period.

For uterine fibroids: the usual dose is one spray twice each day for 3 months. Spray into one nostril in the morning, and the other nostril in the evening (a total of 2 sprays per day). You should use the spray for the first time between the second and fourth day of your period.

For **endometriosis** the longest time for which you should use this medicine is 6 months.

For **uterine fibroids** the longest time for which you should use this medicine is 3 months.

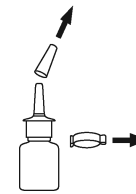
For use in fertility programmes: if you are taking this medicine as part of a fertility programme, the dose is usually one spray to **both** nostrils in the morning, and one spray to **both** nostrils in the evening (4 sprays per day). You may start using the spray on either the second or twenty first day of your menstrual cycle. If you are taking this medicine as part of a fertility programme, your doctor will tell you how long to keep taking your medicine.

Important Tips about using Synarel:

- Your pump should produce a fine mist, which can only happen by a quick and firm pumping action. It is normal to see some larger droplets of liquid within the fine mist. However, if Synarel comes out of the pump as a thin stream of liquid instead of a fine mist, Synarel may not work as well, and you should talk to your pharmacist.
- Be sure to clean the Spray Tip after priming (at the time of the first use). The spray tip should then be cleaned before and after every use. Failure to do this may result in a clogged tip that may cause you not to get the right amount of medicine that is prescribed for you. Always replace the safety clip and the plastic dust cap on the nasal piece after use to help prevent the tip becoming clogged.
- The pump is made to deliver only a set amount of medicine, no matter how hard you pump it.
- Do not try to make the tiny hole in the spray tip larger. If the hole is made larger the pump will deliver a wrong dose of Synarel.

Priming the Spray Pump: Before you use a bottle of Synarel for the first time, you have to prime the spray pump. This only needs to be done once, before you use your first dose.

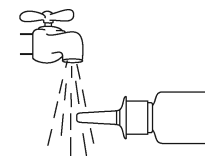
1. Remove and save the safety clip and the plastic dust cap to uncover the nasal piece. Hold the bottle in an upright position away from you with two fingers on the 'shoulders' and your thumb on the bottom of the bottle.



2. Prime the pump by pressing the bottle upwards several times firmly and quickly until the air is expelled and a fine spray appears. This usually requires about 5 - 7 presses. It is not necessary to prime the pump again during subsequent use. You will waste your medicine if you prime the pump every time you use it.



3. Clean the Spray Tip after Priming. Hold the bottle in a horizontal position and rinse the spray tip with warm water, while wiping the tip with your finger or a clean soft cloth for 15 seconds.



Do not clean the spray tip with a pointed object. This could cause an improper dose of the spray to be delivered. Do not remove the pump from the bottle, as this will release the priming pressure.

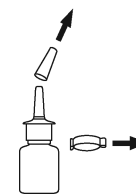
Wipe the tip dry with a clean soft cloth or tissue.

Using the Spray Pump

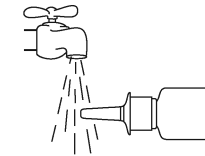
1. Gently blow your nose to clear the nostrils.



2. Remove and save the safety clip and the plastic cap to uncover the nasal piece. Hold the bottle as shown previously.



3. Clean the tip of pump. Hold the bottle in a horizontal position and rinse the spray tip with warm water, while wiping the tip with your finger or a clean soft cloth for 15 seconds.



Do not clean the spray tip with a pointed object. This could cause an improper dose of the spray to be delivered. Do not remove the pump from the bottle, as this will release the priming pressure.

Wipe the tip dry with a clean soft cloth or tissue.

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Nasal Spray Solution
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4. Bend head forward slightly. Close one nostril and put the spray tip into the other, aiming towards the **back and outer side** of your nose.



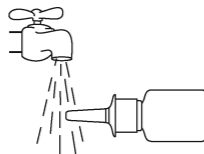
5. Press the bottle firmly up between thumb and fingers **once only** whilst gently breathing in through the nostril. If your doctor has told you to use 4 sprays every day, now spray into your other nostril.



6. Remove the sprayer from the nostril. Bend head backwards for a few seconds to let the spray spread over back of the nose.



7. Clean the tip of pump. Hold the bottle in a horizontal position and rinse the spray tip with warm water, while wiping the tip with your finger or a clean soft cloth for 15 seconds.

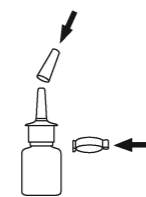


Do not clean the spray tip with a pointed object. This could cause an improper dose of the spray to be delivered. Do not remove the pump from the bottle, as this will release the priming pressure.

Wipe the tip dry with a clean soft cloth or tissue.

Cleaning the spray tip before and after use is important to prevent clogging of the tip that may cause you to get the wrong dose of medicine.

8. Replace the safety clip and the plastic dust cap on the nasal piece. This is important as it helps to prevent the spray tip becoming clogged.



If you use more Synarel than you should

- If you have taken too many sprays at once, or in one day contact your doctor or go to your nearest hospital casualty department immediately.

If you forget to use Synarel

- If you forget to use your spray at the proper time, use it as soon as you remember and use the next spray at your normal time.
- If you miss one or more doses, vaginal bleeding (often called breakthrough bleeding) may occur. Also, release of an egg from the ovary (ovulation) may occur. If you have had sexual intercourse and not used contraception, you could become pregnant. It is then important that you stop taking Synarel and see your doctor to make sure that you are not pregnant. (This is why it is very important to use a barrier method of contraception when you are taking this medicine).

Do not use a double dose to make up for a forgotten dose.

Use your spray as your doctor has told you to.

If you are still not sure, ask your doctor or pharmacist.

It is important to keep taking your spray.

If you have any questions, don't wait until your nasal spray is finished before seeing your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

About 1 in 500 patients may have an allergy to this medicine. If you are allergic to it, you may become short of breath, have chest pain, or a rash which may or may not be itchy. If this happens to you, stop taking Synarel, and tell your doctor straight away.

Other side effects Synarel may cause are listed below by frequency:

Very common side effects: may affect more than 1 in 10 people

- Weight increase
- Swings of emotion
- Sex drive decrease
- Headache
- Hot flushes
- Nasal irritation and/or inflammation
- Acne
- Oily appearance on the skin and the formation of grease scales
- Painful muscles
- Breast size decrease
- Vaginal dryness
- Fluid retention

Common side effects: may affect up to 1 in 10 people

- Allergic reaction which may include shortness of breath, chest pain, swelling of the face or tongue and a rash which may or may not be itchy or an itch sensation
- Itching which may be accompanied by swelling
- Skin rash including hives
- Weight decrease
- Mood changes
- Sex drive increase
- Oestrogen deficiency
- Depression
- Difficulty sleeping (insomnia)
- Tingling or numbing sensation in parts of your body
- High blood pressure (hypertension)
- Low blood pressure (hypotension)

- Abnormal hairiness
- Artificial menopause
- Large discharge of blood from uterus
- Reduction in bone density

Uncommon side effects: may affect up to 1 in 100 people

- Breast size increase
- Hair loss
- Ovarian cyst formation
- Joint pain

Not known side effects: the frequency cannot be estimated from the available data

- Temporary increase in endometriosis
- Inflammation of the lungs (pneumonitis)
- Scarring of the lungs
- Palpitations
- Liver enzyme increases
- Migraine
- Blurred vision
- Enlargement of the ovaries due to excess egg production (OHSS)

Tell your doctor if you are due to have any medical tests as the results may be affected.

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. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Synarel

- 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 the spray bottle after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Keep the bottle upright and in the outer carton. Do not refrigerate or freeze.
- Store in the original container in order to protect from light.
- You should always put the safety clip and the plastic dust cap back on when you are not using the medicine.
- 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 protect the environment.

6. Contents of the pack and other information

What Synarel contains and its package:

The active substance is nafarelin. The Synarel spray liquid contains nafarelin acetate equivalent to a concentration of 2 mg/ml nafarelin in a bottle fitted with a metered spray pump. Each actuation of the spray pump delivers 200 micrograms of nafarelin.

The other ingredients in the spray liquid are sorbitol, benzalkonium chloride (see section 2 "Synarel contains benzalkonium chloride"), glacial acetic acid, purified water and sodium hydroxide or hydrochloric acid to adjust the acidity.

What Synarel looks like and contents of the pack

Synarel Nasal Spray solution is a clear, colourless to slightly yellow, aqueous solution.

Synarel is available in white, high density polyethylene bottles with a 0.1ml metered spray pump, containing 6.5ml (30 sprays) or 10ml (60 sprays). The 30-spray bottle will last for 15 days if you are taking 2 sprays every day and for 7 days if you are taking 4 sprays every day. The 60-spray bottle will last for 30 days if you are taking 2 sprays every day and for 15 days if you are taking 4 sprays every day.

Write the date you should start your next bottle on the box. Make sure you have a new bottle to start to use on that day.

Synarel is also available in PVC-coated glass bottles with an internal conical reservoir in the base and a valois pump, with either an aluminium crimp-on cap or a polypropylene snap-on cap, containing 4ml (30 sprays) or 8ml (60 sprays). These are designed to deliver 30 or 60 sprays respectively (as stated on the pack) and should be disposed of once they have been used for the appropriate number of spray applications.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder

Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24.

Manufacturer

Pfizer Service Company BV
Hoge Wei 10
1930 Zaventem
Belgium

Company contact address

For further information on your medicine contact Medical Information at:
Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland.
Telephone: 1- 800 633 363

Endometriosis Society:

You may be interested to know about the Endometriosis Society. It is a registered charity which offers information and support for women with endometriosis, their families and friends.

The Society cannot answer queries about Synarel but, if you wish to join the Society, or would like more information about endometriosis, please contact:

The Endometriosis Society
Carmichael Centre for Voluntary Groups
Carmichael Avenue
4 Northbrunswick Street
Dublin 7

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