Package leaflet: Information for the user
Synarel® 2mg/ml Nasal Spray
Nafarelin acetate

Read all of this leaflet carefully before you start taking 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 take Synarel
3. How to take 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 or as part of a supervised fertility programme and is for use by women only.
- 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.
- You should take Synarel regularly as instructed by your doctor or nurse, in order for it to be effective.
- Most people do not have serious problems when taking Synarel but side effects can occur – see Section 4 for details. 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.
- 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 acetate 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. It 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 take Synarel

Do not use Synarel

- If you are allergic to nafarelin acetate, gonadotrophin releasing hormone or any of the other ingredients of this medicine (listed in section 6).

- If you are pregnant or may become pregnant whilst taking Synarel. If you are taking Synarel as part of a fertility programme, your pregnancy will be planned to take place after you stop taking 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 are under 18 years of age.

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.

- 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.

Your doctor will advise whether you can still take Synarel.

- After a course of therapy, if further treatment of endometriosis and fibroids with Synarel is needed your bone density may need to be checked.

- Tell your doctor if you are due to have any medical tests as use of this medicine might alter/affect the results.

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 taking a dose of Synarel as they can significantly 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.

Synarel with food and drink

Please refer to section 3.

Pregnancy, breast-feeding and fertility

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

Do not take Synarel if you are breast-feeding.

Driving and using machines

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

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

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 can be taken with or without food.

- Synarel can only be taken/administered through the nose by nasal spray.
- If you sneeze while spraying Synarel, you will need to take another dose of Synarel.

How to use your medicine

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 endometriosis, the longest time for which you should be taking your medicine is 6 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).

If you are taking this medicine as part of a fertility programme, your doctor will tell you how long to keep taking your medicine. This will usually be for no longer than 8 weeks.

Take 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.

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.

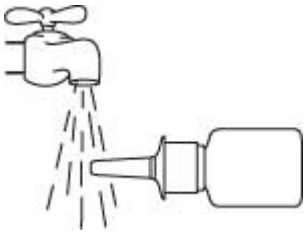
Priming the Spray Pump: Before you use a bottle of Synarel for the first time, you have to prime the spray pump. This only needs to be done once, before you take your first dose.

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.

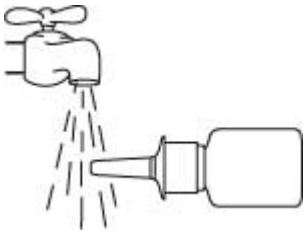
Using the Spray Pump

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.

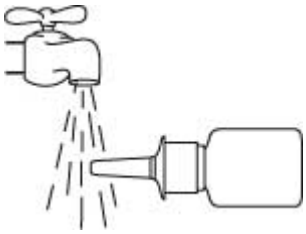
Wipe the tip dry with a clean soft cloth or tissue.

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 take 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.

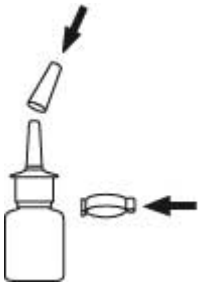


Do not clean the spray tip with a pointed object. This could cause an improper dose of the spray to be delivered. Do not remove the pump from the bottle, as this will release the priming pressure.

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 take your spray at the proper time, take it as soon as you remember and take the next spray at your normal time. Do not take a double dose to make up for a forgotten dose.

- 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.).

- Take 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.

Stop taking Synarel and tell your doctor straight away if you 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.

Synarel may lead to enlargement of the ovaries due to excess egg production (OHSS – Ovarian Hyperstimulation Syndrome). This can lead to pain in the pelvis, stomach or calf, swelling or feeling bloated, passing less urine, difficulty in breathing or an increase in weight. If you experience any of these symptoms, tell your doctor immediately.

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
- oedema

Common side effects: may affect up to 1 in 10 people
- allergic reaction which may include shortness of breath, chest pain and a rash which may or may not be itchy
- itching which may be accompanied by swelling
- skin rash including hives
- oestrogen deficiency
- weight decrease
- depression
- tingling sensation in parts of your body
- hypertension
- hypotension
- excessive hair growth
- artificial menopause
- abnormal bleeding from the vagina
- sex drive increase
- difficulty sleeping (insomnia)
- bone density decreases

Uncommon side effects: may affect up to 1 in 100 people
- hair loss
- joint pain
- breast size increase
- ovarian cyst formation

Not known side effects: the frequency cannot be estimated from the available data
- migraine
- blurred vision
- palpitations

- liver enzyme increases
- short term increase in symptoms of endometriosis
- enlargement of the ovaries due to excess egg production (OHSS)

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 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 Synarel

- You should always put the safety clip and the plastic dust cap back on when you are not using the medicine.

- 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 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 in order to protect from light.

- Do not freeze.

- 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 acetate. 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, 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). 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.

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