

Synarel[®] Nasal Spray

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Synarel?

Synarel contains the active ingredient nafarelin (as acetate). Synarel is used to treat endometriosis. It is also prescribed by specialists as part of in-vitro fertilisation (IVF) programs.

For more information, see Section [1. Why am I using Synarel?](#) in the full CMI.

2. What should I know before I use Synarel?

Do not use if you have ever had an allergic reaction to nafarelin, nafarelin acetate or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant, plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Synarel?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Synarel?

- For endometriosis: 1 spray to one nostril in the morning and 1 spray to the other nostril at night.
- For IVF: 1 spray to each nostril in the morning and 1 spray to each nostril at night.

Instructions for how to prepare and use Synarel can be found in Section [4. How do I use Synarel?](#) in the full CMI.

5. What should I know while using Synarel?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Synarel.• Use a non-hormonal method of birth control such as a diaphragm with contraceptive jelly, an IUD or condoms.• If you are on an IVF program, keep all your appointments so your condition can be monitored.• Speak to your doctor about how Synarel may affect your bones.• If you have hayfever or a runny/blocked nose, ask your doctor about using a nasal decongestant. Nasal decongestants must be used 30 minutes after using Synarel. |
| Things you should not do | <ul style="list-style-type: none">• Do not use the leftover amount in the spray bottle beyond 30 days (if using 2 sprays per day) or beyond 15 days (if using 4 sprays per day).• Do not take birth control pills (oral contraceptives) while you are using Synarel. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Synarel affects you. |
| Drinking alcohol | <ul style="list-style-type: none">• No information available. |
| Looking after your medicine | <ul style="list-style-type: none">• Store it in an upright position in a cool dry place where the temperature stays below 25°C.• Keep away from light.• Do not store it in the freezer or refrigerator. |

For more information, see Section [5. What should I know while using Synarel?](#) in the full CMI.

6. Are there any side effects?

Side effects include: hot flushes, changes in sex drive, vaginal dryness, headaches, mood changes, depression, difficulty sleeping, changes in weight, muscle or joint pain, acne, decreased breast size, irritation inside the nose, increased hair growth, increased oiliness of the skin, or a tingling feeling of the skin. Serious side effects include: symptoms of an allergic reaction, excessive vaginal bleeding, enlargement of the ovaries due to excess egg production, or fluid retention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Synarel[®] Nasal Spray

Active ingredient(s): *nafarelin (as acetate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Synarel. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Synarel.**

Where to find information in this leaflet:

- [1. Why am I using Synarel?](#)
- [2. What should I know before I use Synarel?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Synarel?](#)
- [5. What should I know while using Synarel?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Synarel?

Synarel contains the active ingredient nafarelin (as acetate). Synarel belongs to a group of medicines called pituitary hormone analogues or synthetic gonadotrophin-releasing hormones (GnRH), which work by decreasing the secretion of sex hormones.

Synarel is used for:

- The treatment of a condition called endometriosis.

The lining of the uterus or womb is called the endometrium, and part of it is shed during menstruation (periods). In endometriosis, tissue similar to this lining is found outside the uterus (e.g. ovaries, intestines or other organs in the pelvis), and like normal endometrial tissue, this can bleed during a menstrual cycle.

Although some women with endometriosis may not experience any symptoms, others may have lower back pain, have painful bowel movements, painful periods, or experience pain during intercourse.

Endometrial tissue is affected by the body's hormones, especially oestrogen, which is made by the ovaries. When oestrogen levels are low, the endometrial-like tissue shrinks or may even disappear, and the symptoms of endometriosis ease. Synarel will temporarily reduce the level of oestrogen in the body, thereby temporarily relieving your endometriosis symptoms.

- Women, when prescribed by a specialist, as part of in-vitro fertilisation (IVF) programs.

Synarel assists in decreasing the amount of oestrogen produced by the ovaries. This provides a more controlled situation for subsequent stimulation of the ovaries to produce eggs.

Your doctor may have prescribed Synarel for another purpose. Ask your doctor if you have any questions why Synarel has been prescribed for you.

2. What should I know before I use Synarel?

Warnings

Do not use Synarel if:

- You are allergic to nafarelin, nafarelin acetate or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- You have abnormal vaginal bleeding that your doctor does not know about.
- You are pregnant or suspect that you have become pregnant during therapy. Before starting treatment with Synarel you must have a pregnancy test to confirm that you are not pregnant.
- You are breastfeeding.
- You have had an allergic reaction to any similar medicines which you have used previously to treat your current condition (medicines classified as GnRH or GnRH agonist analogues such as triptorelin, leuprorelin or goserelin).
- The expiry date on the pack has passed or the package shows any sign of tampering.

Check with your doctor if you:

- Have any other medical conditions, such as kidney or liver disease.
- Have or your family has a history of osteoporosis, particularly if this led to fractures,
- Have any problems with your ovaries including a condition called polycystic ovarian syndrome,
- Your periods have either stopped or have been irregular,
- Suffer from hay fever or a blocked or runny nose,
- Are 18 years or younger,
- Take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use Synarel if you are pregnant or breastfeeding.

Check with your doctor if you are pregnant or intend to become pregnant.

If you become pregnant while using Synarel you must see your doctor immediately to discuss the possible risks to the baby and the choices available to you.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Synarel.

4. How do I use Synarel?

How much to use

Your doctor will tell you how much Synarel to use each day and how long your treatment should continue. Follow the instructions provided and use Synarel until your doctor tells you to stop.

Depending on your condition, the usual dose is as follows:

Endometriosis

- The usual dose of Synarel is one spray to one nostril in the morning and one spray to the other nostril at night.
- Your bottle of Synarel contains enough medication to last 30 days following this dosage. If your doctor increases your daily dose of Synarel, then your bottle will not last the same length of time.
- Always ensure that you have sufficient supplies of Synarel so that your treatment is not interrupted.

In-vitro fertilisation (IVF)

- The usual dose of Synarel is one spray to each nostril in the morning and one spray to each nostril at night.
- Your bottle of Synarel contains enough medication to last 15 days following this dosage.

If your doctor has prescribed the use of Synarel any differently then you should discuss this with them.

When to use Synarel

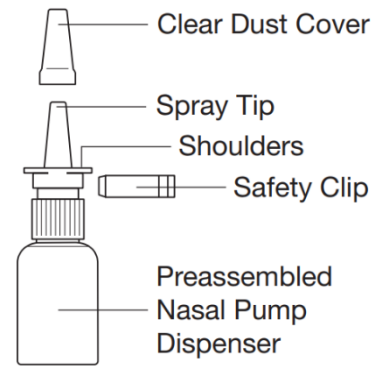
Endometriosis

- Synarel should be started 2 to 4 days after your period begins and continued everyday for 6 months. This is the usual length of Synarel treatment for endometriosis.

In-vitro fertilisation (IVF)

- Synarel should be started on either day 2 or 21 after your period begins and continued strictly as advised by your doctor until told to cease treatment. The length of treatment will depend on the success or failure of in-vitro fertilisation.

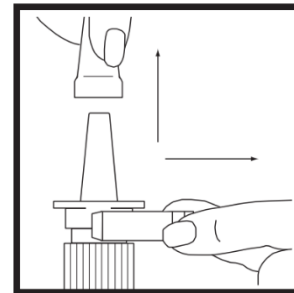
Treatment should be stopped at least 3 days before embryo implantation.



How to prepare Synarel for use

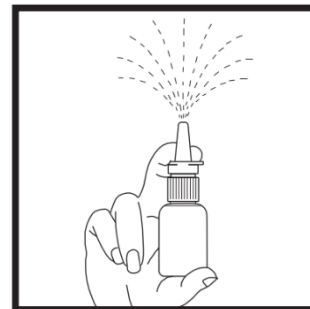
Before you use a bottle of Synarel for the first time you have to prime the spray pump.

CAUTION: Avoid breathing in the spray during priming.



Follow these steps:

1. Remove the safety clip and the clear plastic dust cover from the spray bottle.
2. Put two fingers on the "shoulders" of the spray bottle and put your thumb on the bottom of the bottle.



3. Hold the bottle in an upright position away from you. Apply pressure **EVENLY** to the "shoulders" and push down **QUICKLY AND FIRMLY** until a fine spray occurs. Usually the spray will appear after about 5 to 10 pumps.
4. The pump is now primed.

Priming only needs to be done once when you start using a new bottle of Synarel. You will waste medication if you prime the pump before each use and will not have enough medication for the entire treatment period.

How to use Synarel

IMPORTANT TIPS ABOUT USING SYNAREL

- Your pump should produce a fine mist, which can only be produced by a quick and firm pumping action. It is normal to see some larger droplets of liquid within the

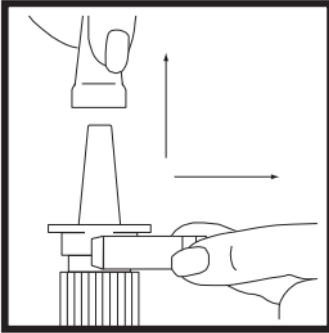
fine mist. However, if your Synarel comes out of the pump as a thin stream of liquid rather than as a fine mist, it may not be as effective and you should return this spray to your pharmacist.

- **DO NOT TRY TO ENLARGE THE TINY HOLE IN THE SPRAYER.** If the hole is enlarged, the pump will deliver an improper dose of Synarel.
- The pump is made to deliver only a set amount of medication, no matter how hard you squeeze it.

Using Synarel



1. Gently blow your nose to clear both nostrils before you use Synarel.



2. Remove the safety clip and clear plastic dust cover from the spray bottle.
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.

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 your head forward a little and put the spray tip into one nostril. (The tip should not reach too far into your nose.) Aim the tip toward the **BACK** and **OUTER SIDE** of your nose.
5. Close the other nostril with your finger.



6. Applying pressure **EVENLY** to the "shoulders", **QUICKLY AND FIRMLY** pump the sprayer **ONE TIME**, at the same time as you sniff in gently.



7. Remove the sprayer from your nose and tilt your head backwards for a few seconds. This lets the spray spread over the back of your nose.

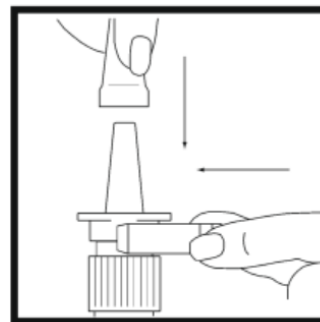
8. Do not spray into the other nostril unless your doctor has specifically instructed you to do so.

9. Clean the tip of the 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.

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.



10. Replace the safety clip and the clear plastic dust cover on the spray bottle.

If you forget to use Synarel

Synarel should be used regularly at the same time each day.

It is very important that you do not miss a single dose of Synarel. However, if you do accidentally miss your dose, follow the directions below.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed.

If you miss one or more doses of Synarel, vaginal bleeding (often called breakthrough bleeding) may occur. Also, release of an egg from the ovary (ovulation) may occur.

If you miss successive doses of Synarel (two or more doses following each other), have had sexual intercourse and have not been using contraceptive measures (as described in the section "What should I know while using Synarel?"), there is a possibility you could become pregnant. See your doctor immediately to check if you are pregnant.

Below are some tips to help you remember to use Synarel regularly.

- Keep your Synarel in a place where you will be reminded to use it each morning and each evening.
- Keep track of each dose on a calendar.
- Make a note on your calendar on the day you start a new bottle of Synarel. You may wish to mark your bottle with this start date.
- Be sure to refill your prescription before the bottle is finished so you have a new bottle on hand to continue your medication.

If you use too much Synarel

If you think that you have used too much Synarel, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

At present, there is very limited experience with cases of Synarel overdose when used as a spray.

If Synarel is accidentally ingested, enzymes in the stomach and bowels will inactivate the medication.

5. What should I know while using Synarel?

Things you should do

- Make sure that all doctors, dentists and pharmacists who are treating you know that you are using Synarel.
- Tell the hospital doctor that you are using Synarel if you need to have an operation, or go to hospital in an emergency.
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using Synarel.
- While using Synarel it is important to use a non-hormonal method of contraception such as a diaphragm with contraceptive jelly, an IUD or condoms.

- If you are on an IVF program, make sure that you keep all appointments so that your condition can be monitored.
- Speak to your doctor about how Synarel may affect your bones.

When you use Synarel, your oestrogen levels will be low. Low oestrogen levels can result in a loss of mineral from bone. During the six month treatment course of Synarel you will lose a small amount of mineral from your bones. In most women a single six month treatment course of Synarel should not be a concern. However, you should discuss the effect of Synarel on bone with your doctor and particularly how this may affect you.

- You should also be aware that repeat treatments close together (that is, more than one treatment period of 6 months) are not recommended. However, if your doctor considers that a second course of treatment is necessary, they will ask you to undergo bone density tests prior to a repeat course of Synarel.

Call your doctor straight away if you:

- Become pregnant while using Synarel.

Things you should not do

- Do not take birth control pills (oral contraceptives) while you are using Synarel. Use another method of contraception such as a diaphragm with contraceptive jelly, an IUD or condoms.
- Do not use the spray bottle beyond 30 days if you are using 2 sprays per day, or beyond 15 days if you are using 4 sprays per day.
- At the end of the recommended 15 or 30 days, a small amount of liquid will be left in the bottle.

Do not try to use the leftover amount because you may get too low a dose of medication, which could interfere with the effectiveness of your treatment. Dispose of the bottle and do not use again.

- Do not use Synarel past the expiry date shown on the label. If you use the spray after the expiry date has passed, it may not work as well.
- Do not give Synarel to anyone else. Your doctor has prescribed it specifically for you and your condition.

Vaginal bleeding or spotting

- For the first two months after starting Synarel, you may experience some irregular vaginal spotting or bleeding. The amount of bleeding and the time this bleeding continues for may vary. This bleeding will usually stop by itself. After the first two months of Synarel treatment, you can expect a decrease in menstrual flow, and your periods may stop altogether. However, if you miss one or more doses of Synarel, you may continue to experience vaginal bleeding.
- See your doctor if you continue to have normal periods after two months of using Synarel.

Hayfever and decongestant

- If you suffer from hayfever or have a cold (which results in a runny or blocked nose) during Synarel treatment, you should see your doctor for a nasal decongestant.
- This decongestant must be used at least 30 minutes after using Synarel so that the absorption of Synarel is not affected.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Synarel affects you.

Drinking alcohol

No information available.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in an upright position in a cool dry place where the temperature stays below 25°C and away from light; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not keep Synarel in the freezer or refrigerator.

Do not use this medicine after the expiry date.

Keep it where young children cannot see or reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

- Dispose of the bottle after the recommended 30 days (if you are using 2 sprays per day) or 15 days (if you are using 4 sprays per day).
- Dispose of any unopened or unused portion of Synarel if it has passed the expiry date shown on the label.

Getting rid of any unwanted medicine

If your doctor tells you to stop using Synarel, you no longer need to use this medicine or it has expired, take it to a pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Due to the initial high levels of oestrogen when you start Synarel therapy, you may experience oestrogen-sensitive migraine or epilepsy. These will resolve provided you continue to use your Synarel as directed.

Long term, continuous use of Synarel may induce a menopausal state.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

| Side effects | What to do |
|--|---|
| <p>Changes to your reproductive health:</p> <ul style="list-style-type: none">• hot flushes• changes in sex drive• vaginal dryness• decreased breast size <p>Feeling unwell due to:</p> <ul style="list-style-type: none">• headaches• irritation inside the nose• mood changes or depression• insomnia (difficulty sleeping) <p>Changes to your body:</p> <ul style="list-style-type: none">• changes in weight• increased hair growth or hair loss• increase or decrease in blood pressure• bone density decrease• abnormal laboratory liver test results <p>Changes to your skin:</p> <ul style="list-style-type: none">• acne• tingling feeling of the skin• increased oiliness of the skin <p>Pain or discomfort:</p> <ul style="list-style-type: none">• muscle pains or• pain and/or swelling of the joints | <p>Speak to your doctor if you have any of these side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <p>Signs of an allergic reaction or difficulty breathing, such as:</p> <ul style="list-style-type: none">• shortness of breath, chest pain or rashes that may or may not be itchy, coughing and wheezing. <p>Changes to your body, such as:</p> <ul style="list-style-type: none">• excessive vaginal bleeding• enlargement of the ovaries due to excess egg production. This can lead to abdominal pain, swelling or feeling bloated, passing less urine, nausea and vomiting, difficulty in breathing or an increase in weight. If you experience any of these symptoms, tell your doctor immediately. | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell, even if it is not on this list.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Synarel contains

| | |
|---|--|
| Active ingredient (main ingredient) | Nafarelin (as acetate) |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• sorbitol• benzalkonium chloride• glacial acetic acid• hydrochloric acid• sodium hydroxide• purified water |

Do not use this medicine if you are allergic to any of these ingredients.

What Synarel looks like

Synarel Nasal Spray nafarelin 2 mg/mL (as acetate) is available in 8 mL bottles (AUST R 48127).

The spray is supplied with a metered spray pump unit which will deliver 60 sprays.

Who distributes Synarel

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in September 2024.