

Synarel[®] Nasal Spray

nafarelin acetate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

Please read this leaflet carefully.

This leaflet answers some common questions about Synarel Nasal Spray.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits.

Your doctor has weighed the risks of you taking Synarel Nasal Spray against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT SYNAREL IS USED FOR

The name of your medicine is Synarel which contains an active ingredient called nafarelin acetate.

Synarel belongs to a group of medicines called pituitary hormone analogues which work by decreasing the secretion of sex hormones.

Specifically, Synarel belongs to a class of drugs known as synthetic gonadotrophin-releasing hormones.

Synarel is usually prescribed by your doctor to treat 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, this lining, or

endometrial tissue, 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, endometrial 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.

Synarel can also be prescribed by a specialist for women as part of in-vitro fertilisation (IVF) programmes. 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.

Do not give Synarel to anyone else.

Your doctor has prescribed it specifically for you and your condition.

BEFORE YOU USE SYNAREL

When you must not use it

Do not use Synarel if:

- you have allergies to Synarel or any ingredients listed in the ingredients section of this leaflet.
- 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 medicine which you have used previously to treat your current condition such as leucoporelin (Lucrin[®]) or goserelin (Zoladex[®]).
- the expiry date on the pack has passed.
- the package shows any sign of tampering.

Before you start to use it

Tell your doctor if:

- you are pregnant or intend to become pregnant. If you should 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.
- you are breastfeeding
- your periods have either stopped or have been irregular

- you have a history of osteoporosis, particularly if this led to fractures
- you have a strong family history of osteoporosis
- you have any problems with your ovaries including a condition called polycystic ovarian syndrome
- you are taking any other medication
- you are 18 years or younger
- you suffer from hay fever or a blocked or runny nose
- you have any other medical condition e.g. kidney, liver disease etc.

Taking other medicines

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

HOW TO 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. 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.

If your doctor increases your daily dose of Synarel, then your bottle will not last the length of time.

Always ensure that you have sufficient supplies of Synarel Nasal Spray so that your treatment is not interrupted.

In-vitro fertilisation

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.

If your doctor has prescribed the use of Synarel Nasal Spray any differently then you should discuss this with him or her.

How to prepare it

Before you use a bottle of Synarel Nasal Spray 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 Nasal Spray. 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 it

IMPORTANT TIPS ABOUT USING SYNAREL NASAL SPRAY

1. 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 Nasal Spray 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.

2. **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.
3. The pump is made to deliver only a set amount of medication, no matter how hard you squeeze it.

Using Synarel Nasal Spray

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

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

When and how long to use it

Endometriosis

You should start using Synarel 2 to 4 days after your period begins and continue to use it everyday for 6 months. This is the usual length of treatment for Synarel.

In-vitro fertilisation

You should start using Synarel on either day 2 or 21 after your period begins and continue to use it 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.

If you forget to use Synarel

It is very important that you do not miss a single dose of Synarel.

However, if you do miss a 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 that you missed.

If you miss one or more doses of Synarel, vaginal bleeding (often called breakthrough bleeding) may occur.

If you miss successive doses of Synarel (two or more doses following each other) and have not been using contraceptive measures (as described in the section "While you are using Synarel"), there is a possibility you could be 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 Nasal Spray 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 Nasal Spray. 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 take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 131 126), or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too much Synarel. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

WHILE YOU ARE USING SYNAREL

Things you must 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 or dentist and your pharmacist that you are using Synarel.

If you become pregnant while using Synarel, see your doctor immediately.

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 programme 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 he or she will ask you to undergo bone density studies prior to a repeat course of Synarel.

Things you must 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 Nasal Spray 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.

Things to be careful of

For the first two months after you start using 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.

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 should be used at least 30 minutes after using Synarel Nasal

Spray so that the absorption of Synarel is not affected.

Synarel is not expected to affect driving or operating of machinery.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Synarel.

Synarel helps most women with endometriosis and/or in an in vitro fertilisation programme but it may have unwanted side effects in some women.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

Continuous treatment may induce a menopausal state.

Tell your doctor if you notice any of the following and they worry you:

- hot flushes
- change in sex drive
- vaginal dryness
- headaches
- mood changes
- depression
- acne
- muscle pains
- decreased breast size
- irritation inside the nose
- pain and/or swelling of the joints
- change in weight
- insomnia

- tingling feeling of the skin
- increased hairiness
- hair loss
- blood pressure change (high or low)

Tell your doctor immediately if you notice any of the following:

- shortness of breath, chest pain or rashes that may or may not be itchy
- coughing and wheezing
- excessive vaginal bleeding
- fluid retention and/or decreased urine output
- liver disease

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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

AFTER USING SYNAREL

Storage

Keep your Synarel Nasal Spray in a safe place away from the sight and reach of children.

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

Keep Synarel in an upright position in a cool dry place where the temperature stays below 25°C and away from light.

Do not put your spray in the freezer or refrigerator.

If you have accidentally stored Synarel in the refrigerator, take it out and leave it at room temperature for at least 1 hour before using it.

Disposal

If your doctor tells you to stop taking Synarel ask your pharmacist what to

do with any nasal spray that is left over.

PRODUCT DESCRIPTION

What it looks like

Synarel Nasal Spray 2 mg/mL is available in 8 mL bottles.

Ingredients

- each 8 mL bottle contains 2 mg/mL nafarelin (as acetate) as the active ingredient
- inactive ingredients include sorbitol, benzalkonium chloride, glacial acetic acid, hydrochloric acid, sodium hydroxide, and purified water.

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

Identification

Synarel Nasal Spray can be identified by the Australian Register Number on the carton label.

Synarel Nasal Spray -
AUST R 48127

Supplier

Synarel is distributed in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll free number:1800 675 229

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