

PART III: CONSUMER INFORMATION**SYNAREL™
(nafarelin acetate nasal solution)**

This leaflet is part III of a three-part "Product Monograph" published when SYNAREL™ (nafarelin acetate) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SYNAREL™. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

SYNAREL is used in the treatment of endometriosis, including pain relief and reduction of endometriosis lesions. The treatment is recommended for a period of 6 months only.

What it does:

SYNAREL temporarily reduces estrogen in the body, thereby temporarily relieving the symptoms of endometriosis.

When it should not be used:**Do not take SYNAREL if you:**

- are allergic to nafarelin acetate, or any similar gonadotropin-releasing hormone (GnRH) analogue, or any of the ingredients in SYNAREL.
- are pregnant or think that you are pregnant;
- are planning to become pregnant;
- have abnormal vaginal bleeding of unknown cause;
- are breastfeeding.

What the medicinal ingredient is:

Nafarelin acetate.

What the nonmedicinal ingredients are:

Benzalkonium chloride, glacial acetic acid, hydrochloric acid, sorbitol, sodium hydroxide, purified water.

What dosage forms it comes in:

Each 8 mL bottle of SYNAREL (nafarelin acetate) contains nafarelin acetate nasal solution 2 mg/mL. Each bottle is supplied with a metered spray pump.

The 8 mL bottle contains enough solution for 60 sprays, enough to last 30 days using two sprays per day. After the stated number of sprays has been delivered a small amount of

liquid may be left in the bottle. Do not try to use up that leftover amount because you might get too low a dose, which could interfere with the effectiveness of your treatment. Dispose of the bottle and do not reuse.

WARNINGS AND PRECAUTIONS

Signs and symptoms of endometriosis can worsen at the beginning of therapy with SYNAREL.

Menstruation should stop with use of SYNAREL. During the first 2 months of SYNAREL use, vaginal bleeding (often called breakthrough bleeding) may occur. This may also occur if you miss one or more doses of SYNAREL. You should advise your doctor or pharmacist, if regular menstruation persists.

You must use a non-hormonal method of birth control while taking SYNAREL to prevent pregnancy. You should discuss effective non-hormonal methods of birth control with your doctor. If you think you are pregnant while taking SYNAREL, you should stop using the drug and contact your doctor immediately. SYNAREL may hurt the unborn baby. SYNAREL is not recommended for use in a patient younger than 18 years of age.

BEFORE you use SYNAREL talk to your doctor or pharmacist if:

- you are pregnant or think that you are pregnant
- you are planning to become pregnant
- you are breastfeeding
- you have or have family history of osteoporosis, or use drug that can reduce bone mass such as anticonvulsants, corticosteroid, or use alcohol and/or tobacco. SYNAREL can cause thinning of the bone.

Retreatment of SYNAREL is not recommended, especially if you are at a high risk of your bones becoming thin (osteoporosis).

INTERACTIONS WITH THIS MEDICATION

Tell your doctor and pharmacist if you are taking, have been taking, or are planning to take any other medicines, including non-prescription drugs.

You may use a nasal decongestant spray while you are being treated with SYNAREL if you follow these simple rules. Use SYNAREL first. Wait at least 30 minutes after using SYNAREL before you use the decongestant spray.

PROPER USE OF THIS MEDICATION

REMEMBER: This medication is for **YOU**. Never give it to others. It may harm them even if their symptoms are the same as yours.

Take SYNAREL as instructed by your doctor.

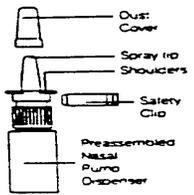
Usual Dose:

1 spray (200mcg) in one nostril the morning and 1 spray (200 mcg) in the other nostril in the evening, about 12 hours apart.

HOW TO USE YOUR SYNAREL NASAL SPRAY UNIT

To Prime the Pump:

CAUTION: Avoid breathing in the spray during priming.



Before you use a bottle of SYNAREL nasal spray **for the first time**, you have to prime the spray pump. Follow these steps:

1. Remove the safety clip and the 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.



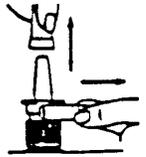
3. Point the tip of the bottle away from you and push the bottle -- quickly and firmly 7-10 times -- with your thumb, until a fine spray appears. Usually the spray will appear after about 7 pumps.

To Use SYNAREL:

1. Gently blow your nose to clear both nostrils before you use SYNAREL nasal spray.



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



3. 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.



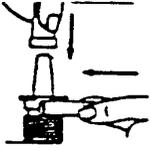
4. Close the other nostril with your finger.



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



6. 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.
7. Wipe tip of pump with a soft cloth or tissue after each use. Replace the safety clip and plastic dust cover on the spray bottle.



To Clean:

1. Be sure to clean the spray tip after every use. Failure to do so may result in a clogged tip that could cause improper dose delivery.
2. Hold bottle in horizontal position. Rinse spray tip with warm water while wiping the tip with your finger or soft cloth for 15 seconds.
3. Wipe spray tip with a soft cloth or tissue to dry. Replace the safety clip and plastic dust cover on the spray bottle.
4. **DO NOT ATTEMPT TO CLEAN SPRAY TIP USING A POINTED OBJECT. DO NOT ATTEMPT TO DISASSEMBLE PUMP.**

Overdose:

If you take too much of the medication, contact healthcare professional, regional Poison Control Centre or hospital emergency department immediately, even if there are no symptoms.

Missed Dose:

TREATMENT WITH SYNAREL MUST BE UNINTERRUPTED – WITH NO MISSED DOSES

Here are some suggestions to help you remember:

- 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**.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Signs and symptoms of endometriosis can worsen at the beginning of therapy with **SYNAREL**.

Your menstrual flow will decrease at the beginning of treatment, then stop altogether later when the body’s production of estrogens decreases.

Very common side effects are hot flashes, decreased interest in sex, headache, vaginal dryness, mood changes, acne, muscle pain, irritation of the tissues inside the nose, and reduction in breast size. Common side effects are nervousness, insomnia, dandruff, weight gain, swelling, gastrointestinal fullness, nausea, altered taste, breast pain,

depression, excessive hair growth, dry skin, dizziness, vertigo, pain during or after intercourse, weight loss, joint pain, increased appetite, loss of appetite, nose bleed, conjunctivitis, weakness, and increased interest in sex. Uncommon side effects are incoordination, neurosis, increased sweating, hair loss, skin discolouration, flat red rash, enlarged breasts, herpes simplex, menstrual disorder, cystitis, painful or difficultly urinating, loss of bladder control, vaginal bleeding, muscle weakness, constipation, diarrhea, gastritis, vomiting, dry nose, sinusitis, voice alteration, ear pain, eye pain, mucous membrane disorder, palpitation.

Ovarian hyperstimulation syndrome (excessive stimulation of egg production in the ovaries) has also been observed.

Check with your doctor or pharmacist right away if you have **any** bothersome or unusual effects while taking **SYNAREL**.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Drug sensitivity (shortness of breath, chest pain, urticaria, rash and pruritus)	√		√
Uncommon	Vaginal hemorrhage	√		√
	Ovarian hyperstimulation syndrome (excessive stimulation of egg production in the ovaries. Symptoms can include abdominal bloating, pain in the abdomen, weight gain, nausea, vomiting, diarrhea)		√	

This is not a complete list of side effects. For any unexpected effects while taking SYNAREL, stop taking the drug and contact your doctor or pharmacist.

HOW TO STORE IT

Store upright between 15 - 25°C. Protect from light and freezing.

You should not use your medication after the expiration date printed on the carton and label.

Keep all medications out of the reach of children. This medication could harm them.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Consumer Side Effect Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789, or**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Consumer Side Effect Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

***NOTE:* Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.**

MORE INFORMATION

This document plus the full Product Monograph, prepared for Health Professionals can be found at:

<http://www.pfizer.ca>

or by contacting the sponsor, Pfizer Canada Inc., at 1-800-463-6001.

This leaflet was prepared by Pfizer Canada Inc.

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