PART III: CONSUMER INFORMATION

SUPREFACT®
Buserelin Acetate
Injection, 1 mg/mL

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

ABOUT THIS MEDICATION

What the medication is used for:
SUPREFACT injection is used for the palliative treatment (relieves pain and symptoms but not intended to cure disease) of patients with advanced prostate cancer (Stage D).

What it does:
SUPREFACT treatment results in decreasing the levels of your sex hormones.

Prostate cancer cells appear to need testosterone for their growth. When the body's supply of testosterone is lowered, prostate cancer usually shrinks or stops growing, which may result in a reduction of symptoms related to the disease.

When it should not be used:

- If you have experienced a prior allergic reaction to buserelin acetate or if you are allergic to any of the components of SUPREFACT (see the section titled: "What the nonmedicinal ingredients are" below) or component of the container.
- If you do not have a hormone-dependent prostate cancer or if you have undergone castration.
- The solution for injection should not be used in pregnancy and breast-feeding women.

What the medicinal ingredient is:
Buserelin Acetate

What the nonmedicinal ingredients are:
Benzyl alcohol, monobasic sodium phosphate buffer, sodium chloride, sodium hydroxide.

What dosage forms it comes in:
Each mL of sterile aqueous injection solution contains: 1.00 mg buserelin as buserelin acetate.

SUPREFACT is packaged in clear glass multi-dose vials of 10mL containing 5.5 mL.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

SUPREFACT should be prescribed and managed by a doctor experienced with this type of drugs.

SUPREFACT may cause:

- worsening of symptoms of prostate cancer at the beginning of the treatment
- bone thinning (osteoporosis)

Before you use SUPREFACT talk to your doctor or pharmacist if you have conditions described below:

- Low red blood cell count (anemia),
- Family history of severe osteoporosis, have low bone mineral density (BMD), or taking any medication that can cause thinning of the bones,
- Heart disease, or have a heart condition called 'long QT syndrome',
- High blood pressure,
- Diabetes (high blood sugar), SUPREFACT may affect your blood glucose level and you may need to test your blood sugar more frequently while taking SUPREFACT,
- Asthma or have had any severe allergic reactions,
- Depression or a history of depression.

SUPREFACT may cause dizziness. Do not drive a car or operate machinery until you know how the drug affects you.

The use of SUPREFACT over a long period of time may lead to hypogonadism (inability of the testicle to produce testosterone and/or sperm). It is not known if the effect will reverse when SUPREFACT is discontinued.

INTERACTIONS WITH THIS MEDICATION

- Drugs that may interact with SUPREFACT and may cause a change in heart rhythm (QT prolongation) include, but are not limited to:
  – antiarrhythmic drugs (used to treat abnormal heart rhythm) such as: quinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide, dronedarone, flecainide, propafenone
  – antipsychotic drugs (used to treat mental disorders) such as: chlorpromazine
  antidepressant drugs (used to treat depression) such as: amitryptiline, nortryptiline
  – opioid drugs, such as: methadone
  – antibiotics, such as: erythromycin, clarithromycin,

azithromycin, moxifloxacin
- antimalarials, such as: quinine
- drugs belonging to a class called 5-HT3 antagonists, such as: ondansetron.
- drugs belonging to a class called beta-2 agonists, such as: salbutamol

Your doctor will be able to advise you what to do if you are taking any of these medicines. Your doctor may also perform some blood tests.

- SUPREFACT may reduce the effect of drugs used to treat high blood pressure. It is recommended that blood pressure be monitored regularly in these patients.

- SUPREFACT may reduce the effect of drugs used to treat diabetes. Blood glucose levels should be checked regularly in diabetic patients.

- Talk to your doctor or pharmacist if you take any other medications or before using over-the-counter medicines or herbal products. Your doctor or pharmacist will evaluate the risk of interaction with this medication.

PROPER USE OF THIS MEDICATION

It is important that you follow your doctor's instructions carefully.

If you are taking SUPREFACT by injection three times each day, try and space the injections eight (8) hours apart. If you are taking SUPREFACT injection once daily inject it the same time of day every day.

How to use SUPREFACT:
The SUPREFACT vial is supplied with a plastic cap which can be removed by pressing upwards with the thumb. This cap serves to ensure that the vial has not been previously entered. After removal (the cap can be discarded) the rubber diaphragm of the vial is exposed. Proceed:

1. Wash your hands, with soap and water, and dry on a clean towel.

2. Clean the rubber diaphragm of the SUPREFACT vial with a cotton swab previously dipped in alcohol. Leave to dry.

3. Select an appropriate sterile, disposable syringe and needle assembly (your doctor or pharmacist will help you select a syringe of appropriate bore and cylinder graduations) and remove it from its sterile packaging.

4. Draw the syringe piston as far back as the volume (see syringe cylinder graduation) of solution you wish to withdraw from the vial.

5. Remove the needle sheath (protector).

6. Without touching the needle with your fingers, push the needle through the centre of the rubber diaphragm of the vial.

7. Push on the syringe plunger so that the selected air volume is expelled into the vial.

8. Keeping the needle in the vial, invert the vial into the vertical position adjusting the needle tip to a position below the surface of the solution in the vial.

9. Draw the required solution from the vial by withdrawing the syringe piston.

10. Carefully withdraw the needle and syringe assembly from the vial.
11. Choose your injection site (vary the site for each injection as discussed with your doctor or pharmacist) and clean the skin with an alcohol impregnated swab.

12. Pinch the site, if you wish, between index finger and thumb and, with the needle at an angle introduce the needle quickly under the skin as far as possible.

13. Withdraw the syringe piston a little and, if no blood is withdrawn into the syringe, then push on the piston steadily to inject the solution.

14. Upon completion of the injection, and resting the alcohol-impregnated swab over the needle entry site, remove the needle in a reverse fashion of the entry motion. Hold swab to injection site for a few seconds, then remove.

15. Discard needle and syringe assembly along with the swab in a safe manner. Return the SUPREFACT vial to its storage area.

Overdose:

If you have injected too much SUPREFACT, immediately see your doctor, go to your nearest hospital emergency department or contact a regional Poison Control Centre immediately. Do this even if there are no signs of discomfort or poisoning.

Missed Dose:
Should you forget to take a dose, inject it as soon as you can. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

SUPREFACT treatment results in suppression of your sex hormones. Consequently, the side effects you may experience may be related to this hormone-suppressing action of the drug. Your side effects may include hot flushes and loss of sex drive

In rare instances, you may experience an increase in your disease process such as pain, or increased pain, or increased difficulty in urinating. Should you experience events such as these, contact your doctor without delay.

Occasionally, reddening, itching or swelling may occur at the SUPREFACT injection site. These occurrences can be minimized by rotating the site of injection. In the event of persisting problems of this nature consult your doctor.

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 pharma-cist
		Only if severe	In all cases	
Common	**Hot flushes**	√		
	Loss of libido	√		
	Impotence	√		
	Gastrointestinal problems	√		
	Skin itching	√		
	Abnormal enlargement of the breasts	√		
	Injection site reactions (pain, irritation, swelling, urticaria)	√		
Uncommon	**Increase in your disease signs and symptoms such as pain or increased difficulty in urinating**		√	

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
Unknown frequency	**A change in heart rhythm (QT prolongation). QT prolongation symptoms include sensation of skipped heart beats or rapid or forceful beats, shortness of breath, chest discomfort, and feeling faint**			√

This is not a complete list of side effects. For any unexpected effects while taking* SUPREFACT, *contact your doctor or pharmacist.

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 Canada Vigilance 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, Canada Vigilance 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.

HOW TO STORE IT

SUPREFACT should be kept at controlled room temperature, between 15 and 25°C. Do not permit the product to freeze and do not expose it to sources of heat. Protect from light.

Do not use SUPREFACT beyond the expiry date printed on the label.

The product can be kept up to 14 days after the first opening when stored at room temperature.

KEEP MEDICINES OUT OF REACH OF CHILDREN.

MORE INFORMATION

Your physician, nurse and pharmacist are always your best source of information about your condition and treatment. If you have additional questions or concerns, be sure to ask them.

This document plus the full product monograph, prepared for health professionals can be found online at www.sanofi.ca or by contacting sanofi-aventis Canada Inc., at: 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last revised: August 10, 2015

PART III: CONSUMER INFORMATION

SUPREFACT®
Buserelin Acetate
Nasal Solution 1 mg/mL

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

ABOUT THIS MEDICATION

What the medication is used for:
SUPREFACT nasal solution is used for the palliative treatment (relieves pain and symptoms but not intended to cure disease) of patients with advanced prostate cancer (Stage D) **(maintenance therapy ONLY).**

SUPREFACT nasal solution is also used in women for the treatment of endometriosis (disease associated with premenstrual pain and painful menstruation).

What it does:
SUPREFACT treatment results in decreasing the levels of your sex hormones.

Prostate Cancer
Prostate cancer cells appear to need testosterone for their growth. When the body's supply of testosterone is lowered, prostate cancer usually shrinks or stops growing, which may result in a reduction of symptoms related to the disease.

Endometriosis
Reduction of the sex hormone can result in a reduction of the symptoms of endometriosis.

When it should not be used:
General

- If you have experienced a prior allergic reaction to buserelin acetate or if you are allergic to any of the components of SUPREFACT (see the section titled: "What the nonmedicinal ingredients are" below) or component of the container.

Prostate Cancer

- If you do not have a hormone-dependent prostate cancer or if you have undergone castration.

Endometriosis

- If you are pregnant or if you are breast-feeding.
- If you have abnormal vaginal bleeding of unknown cause.

What the medicinal ingredient is:
Buserelin Acetate

What the nonmedicinal ingredients are:
Benzalkonium chloride, citric acid/sodium citrate buffer, sodium chloride.

The metered-dose pump contains no propellants.

What dosage forms it comes in:
Each mL of aqueous intranasal solution contains: 1.00 mg buserelin as buserelin acetate.

SUPREFACT is packaged in amber glass bottles of 10.0 mL for intranasal administration via the metered-dose pump provided.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

SUPREFACT should be prescribed and managed by a doctor experienced with this type of drugs.

SUPREFACT may cause:

- worsening of the symptoms of prostate cancer at the beginning of the treatment
- bone thinning (osteoporosis)

Before you use SUPREFACT talk to your doctor or pharmacist if you have conditions described below:

- Low red blood cell count (anemia),
- Family history of severe osteoporosis, have low bone mineral density (BMD), or taking any medication that can cause thinning of the bones,
- Heart disease, or have a heart condition called 'long QT syndrome',
- High blood pressure,
- Diabetes (high blood sugar): SUPREFACT may affect your blood glucose level and you may need to test your blood sugar more frequently while taking SUPREFACT,
- Asthma or have had severe allergic reactions,
- Depression or a history of depression,
- Pregnant or plan to become pregnant,
- Breastfeeding,
- Vaginal bleeding. During treatment with SUPREFACT, menstruation stops. If regular menstruation persists, contact your doctor. Breakthrough menstrual bleeding may occur if treatment with SUPREFACT is interrupted.

Oral contraceptives must be discontinued before starting treatment with SUPREFACT. Therefore, pregnancy must be avoided by the use of non-hormonal methods of contraception (e.g. condoms).

The use of SUPREFACT over a long period of time may lead to hypogonadism (inability of the testicle to produce testosterone and/or sperm). It is not known if the effect will reverse when SUPREFACT is discontinued.

INTERACTIONS WITH THIS MEDICATION

- Drugs that may interact with SUPREFACT and may cause a change in heart rhythm (QT prolongation) include, but are not limited to:
  - antiarrhythmic drugs (used to treat abnormal heart rhythm) such as: quinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide, dronedarone, flecainide, propafenone
  - antipsychotic drugs (used to treat mental disorders) such as: chlorpromazine
  - antidepressant drugs (used to treat depression) such as: amitryptiline, nortryptiline
  - opioid drugs, such as: methadone
  - antibiotics, such as: erythromycin, clarithromycin, azithromycin, moxifloxacin
  - antimalarials, such as: quinine
  - drugs belonging to a class called 5-HT3 antagonists, such as: ondansetron.
  - drugs belonging to a class called beta-2 agonists, such as: salbutamol

  Your doctor will be able to advise you what to do if you are taking any of these medicines. Your doctor may also perform some blood tests.

- SUPREFACT may reduce the effect of drugs used to treat high blood pressure. It is recommended that blood pressure be monitored regularly in these patients.

- SUPREFACT may reduce the effect of drugs used to treat diabetes. Blood glucose levels should be checked regularly in diabetic patients.

- Talk to your doctor or pharmacist if you take any other medications or before using over-the-counter medicines or herbal products. Your doctor or pharmacist will evaluate the risk of interaction with this medication.

PROPER USE OF THIS MEDICATION

It is important that you follow your doctor's instructions carefully.

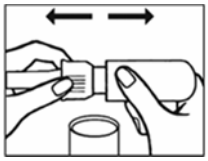
How to use SUPREFACT:

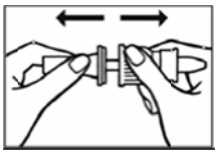
The SUPREFACT bottle is supplied in a carton complete with the required administration device, a metered-dose pump (nebulizer) which has a mechanical (spring-loaded) action. The pump contains no chemical propellants.

To administer SUPREFACT using this pump proceed as follows, bearing in mind that these instructions are not intended to supersede instructions you may have received from your doctor:

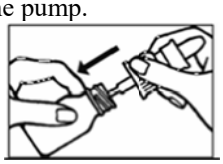
1. Wash your hands with soap and water and dry on a clean towel.

2. Remove the dose pump from the enclosed transparent plastic container; pull off both protective caps on top and bottom carefully.

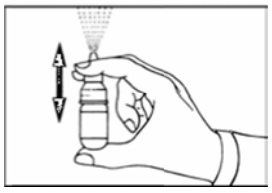




3. Remove SUPREFACT bottle from the container. Unscrew cap and discard it. Securely screw dose pump into glass bottle. The interior of the bottle is tapered towards the bottom. That feature, along with the concaved end to the pump tube, means that the pump can still usefully operate even though small quantities of solution (drug) remain. Do not tilt bottle when using the pump.



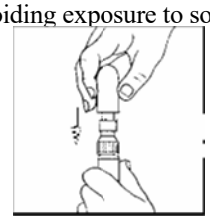
4. Before first application, hold bottle with pump in a vertical position and pump several times until a uniform mist is released. This pump-priming may be necessary again after the pump has been stored between use.



5. Keeping the pump and bottle in a vertical position, place the pump aperture or nozzle into the nostril (if necessary, clean the nose prior to SUPREFACT administration) and operate as before, once. Gentle sniffing aids the distribution of SUPREFACT over the nasal

passages from where it is absorbed. Nasal congestion will not prevent SUPREFACT absorption/use, if the nasal spray is administered correctly. In those cases, however, it is recommended that the nose be blown thoroughly before using the spray.

6. After use, the pump remains in the bottle with its protective cap in position. Store bottle in an upright position at room temperature (between 15-25°C) avoiding exposure to sources of heat.



7. Follow your doctor's instructions closely. Do not make any changes in the treatment pattern unless you have first discussed the subject with the doctor.

Overdose:

If you have taken too much SUPREFACT, immediately see your doctor, go to your nearest hospital emergency department or contact a regional Poison Control Centre immediately. Do this even if there are no signs of discomfort or poisoning.

Missed Dose:

Should you forget to take a dose, administer it as soon as you can. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

SUPREFACT treatment results in suppression of your sex hormones. Consequently, the side effects you may experience may be related to this hormone-suppressing action of the drug.

Prostate cancer

Your side effects may include hot flushes, impotence and loss of sex drive. If these continue to make you feel uncomfortable, consult your doctor.

Occasionally headaches may be troublesome and nasal irritation or dryness may appear. In the event of persisting problems consult your doctor.

Endometriosis

Your side effects may include hot flushes, vaginal dryness, menorrhagia (abundant vaginal bleeding), headaches and loss of sex drive. If these continue to make you feel uncomfortable, consult your doctor.

The following side effects may also appear: dizziness, application site reaction, depression, emotional lability, weakness, nausea or acne.

Occasionally gastrointestinal disorders, weight gain, edema (fluid held in the tissue), arthralgia (paint in join), insomnia or breast pain may appear.

In the event of persisting problems consult your doctor.

If you experience an increase in the disease signs and symptoms, consult your doctor immediately.

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	
Common	**Hot flushes**	√		
	Loss of libido	√		
	Headache	√		
	Nasal irritation	√		
	Nasal dryness	√		
Uncommon	**Increase in your disease signs and symptoms**		√	
Unknown frequency	**A change in heart rhythm (QT prolongation). QT prolongation symptoms include sensation of skipped heart beats or rapid or forceful beats, shortness of breath, chest discomfort, and feeling faint**			√

This is not a complete list of side effects. For any unexpected effects while taking* SUPREFACT, *contact your doctor or pharmacist.

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 Canada Vigilance 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, Canada Vigilance 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.

HOW TO STORE IT

SUPREFACT should be kept at controlled room temperature, between 15-25°C.

Do not permit the product to freeze and do not expose it to sources of heat. Protect from light.

The product can be kept up to 5 weeks after the first opening when stored at room temperature.

Do not use SUPREFACT beyond the expiry date printed on the label.

KEEP MEDICINES OUT OF REACH OF CHILDREN.

IMPORTANT:
PLEASE READ