

## PART III: CONSUMER INFORMATION

### Pr ZEMPLAR® Paricalcitol Capsules

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

#### ABOUT THIS MEDICATION

##### What the medication is used for:

ZEMPLAR® Capsules are used in the prevention and treatment of secondary hyperparathyroidism (high levels of parathyroid hormone which can cause bone problems) in chronic renal failure patients on peritoneal or hemodialysis (Chronic Kidney Disease Stage 5).

##### What it does:

ZEMPLAR® Capsules are a synthetic vitamin D analogue and are used to replace the body's naturally produced active form of vitamin D. In healthy people, the active form of vitamin D is naturally produced by the kidneys but in kidney failure, the production of the active vitamin is reduced which can cause low levels of calcium and high levels of parathyroid hormone in the blood.

##### When it should not be used:

ZEMPLAR® Capsules should not be used:

- If you are allergic to vitamin D or have developed evidence of vitamin D toxicity. Symptoms which can occur after receiving too much vitamin D include: confusion, feeling sleepy, weakness, muscle pain, bone pain, constipation, nausea, vomiting, stomach pains, itchy skin, increased thirst, and increased urination.
- If you suffer from hypercalcemia (high levels of calcium in your blood)
- If you are allergic to any of the product's ingredients

##### What the medicinal ingredient is:

The active substance is paricalcitol.

##### What the important nonmedicinal ingredients are:

ZEMPLAR® Capsules also contains medium chain triglycerides, alcohol, butylated hydroxytoluene, gelatin, glycerin, titanium dioxide, ink, Opacode® WB, black, iron oxide red (2 mcg capsules only), iron oxide yellow (2 mcg and 4 mcg capsules), iron oxide black (1 mcg capsules only), purified water.

##### What dosage forms it comes in:

Each capsule contains either 1 mcg, 2 mcg or 4 mcg of paricalcitol. The 1 mcg capsule is an oval, gray, soft gelatin capsule imprinted with ☐ and ZA. The 2 mcg capsule is an oval, orange-brown, soft

gelatin capsule imprinted with ☐ and ZF. The 4 mcg capsule is an oval, gold soft gelatin capsule imprinted with ☐ and ZK.

ZEMPLAR® Capsules is available in bottles containing 30 capsules each.

#### WARNINGS AND PRECAUTIONS

**BEFORE you use ZEMPLAR® Capsules talk to your doctor or pharmacist if:**

- § You are pregnant or if you are breast feeding. Ask your doctor or pharmacist for advice.

#### INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including the medicine you can buy without a prescription, natural health products, vitamin or mineral supplements.

**Drugs that may interact with ZEMPLAR® Capsules include:**

- Products containing phosphate or vitamin D.
- Products which contain aluminum or magnesium, these would include antacids (stomach medicine) or phosphate binders (used to remove phosphate from the blood).
- Digitalis compound e.g., digoxin or digitoxin (medicines used in certain heart conditions), thiazide diuretics (a type of water tablet) or medicines which contain high levels of calcium.
- Products used to treat fungal infections (e.g., ketoconazole).

#### PROPER USE OF THIS MEDICATION

##### Usual dose:

The dosage of ZEMPLAR® Capsules varies for each patient. Your doctor will decide on the appropriate dose for you. ZEMPLAR® Capsules are to be taken three times a week (every other day) and may be taken with or without food.

##### Missed dose:

If you miss a dose, do not take a double dose. The next dose should be taken as usual.

##### Overdose:

If you take more ZEMPLAR® Capsules than you should, contact your doctor or an emergency room of the nearest hospital.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

The most common side effects experienced: *These might affect between 1 and 10 in every 100 people.* High blood levels of calcium and phosphate; low blood levels of calcium, loss of appetite, diarrhea, dizziness, acne, breast pain, itchy skin and a change in your sense of taste.

Uncommon side effects: *These might affect less than 1 in every 100 people.* Allergic reaction, constipation, dry mouth, indigestion, gastrointestinal disorder or upset stomach (gastritis), dizziness, rash, hives, leg cramps and unusual taste. The results of blood tests may show raised liver enzymes.

Too much ZEMPLAR® Capsules can cause hypercalcemia (higher than normal levels of calcium in the blood, which can be harmful). To help prevent this your blood will be tested frequently early in your treatment, so that your doctor can adjust the dose of ZEMPLAR® Capsules to suit you.

Early signs and symptoms of hypercalcemia associate with vitamin D overdose include weakness, headache, feeling sleepy or sick, vomiting, dry mouth, constipation, muscle pain, bone pain and metallic taste.

Symptoms of hypercalcemia associated with vitamin D overdose which may develop over a longer period include a lack of appetite, feeling sleepy, weight loss, sore eyes, runny nose, itchy skin, feeling hot and feverish, decreased sex drive, calcium deposits and severe abdominal pain (due to an inflamed pancreas).

**If you experience any other unusual or unexpected symptoms while receiving ZEMPLAR® Capsules tell 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	
Uncommon	Gastrointestinal disorder (diarrhea, abdominal pain)		T	
	Dizziness		T	T

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

**HOW TO STORE IT**

ZEMPLAR® Capsules should be stored between 15 and 25°C.

**REPORTING SUSPECTED SIDE EFFECTS**

**To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:**

toll-free telephone: 866-234-2345  
 toll-free fax 866-678-6789  
 By email: [cadmp@hc-sc.gc.ca](mailto:cadmp@hc-sc.gc.ca)

**By regular mail:**  
**National AR Centre**  
**Marketed Health Products Safety and Effectiveness**  
**Information Division**  
**Marketed Health Products Directorate**  
**Tunney's Pasture, AL 0701C**  
**Ottawa ON K1A 0K9**

*NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.abbott.ca> or by contacting the sponsor, Abbott Laboratories, Limited at 1-800-699-9948.

This leaflet was prepared by Abbott Laboratories, Limited.

Last revised: November 21, 2007

## PART III: CONSUMER INFORMATION

### Pr ZEMPLAR® Paricalcitol Injection USP

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

#### ABOUT THIS MEDICATION

##### What the medication is used for:

ZEMPLAR® Injection USP is used in the prevention and treatment of secondary hyperparathyroidism (high levels of parathyroid hormone which can cause bone problems) in chronic renal failure patients on hemodialysis (Chronic Kidney Disease Stage 5).

##### What it does:

ZEMPLAR® Injection USP is a synthetic vitamin D analogue and is used to replace the body's naturally produced active form of vitamin D. In healthy people, the active form of vitamin D is naturally produced by the kidneys but in kidney failure, the production of the active vitamin is reduced which can cause low levels of calcium and high levels of parathyroid hormone in the blood.

##### When it should not be used:

ZEMPLAR® Injection USP should not be used:

- If you are allergic to vitamin D or have developed evidence of vitamin D toxicity. Symptoms which can occur after receiving too much vitamin D include: confusion, feeling sleepy, weakness, muscle pain, bone pain, constipation, nausea, vomiting, stomach pains, itchy skin, increased thirst, and increased urination.
- If you suffer from hypercalcemia (high levels of calcium in your blood)
- If you are allergic to any of the product's ingredients

##### What the medicinal ingredient is:

The active substance is paricalcitol.

##### What the important nonmedicinal ingredients are:

ZEMPLAR® Injection USP also contains alcohol (20% v/v), propylene glycol and water for injection.

##### What dosage forms it comes in:

ZEMPLAR® Injection USP is available as a liquid (containing 5 micrograms of paricalcitol per 1 mL) and packaged in ampoules or Fliptop vials as follows:

- Ampoules containing 1 mL or 2 mL
- Fliptop vials containing 1 mL or 2 mL

#### WARNINGS AND PRECAUTIONS

This product contains 20% ethanol. The amount of ZEMPLAR® Injection USP given to you could contain up to 1.3 grams of alcohol. This could be harmful to people who suffer from liver disease, alcoholism, epilepsy, brain injury or disease as well as for pregnant women and children. It may modify or increase the effect of other medicines.

**BEFORE you use ZEMPLAR® Injection USP talk to your doctor or pharmacist if:**

- § You are pregnant or if you are breast feeding. Ask your doctor or pharmacist for advice.
- § You have liver disease
- § You drink alcohol
- § You have seizures (epilepsy or brain injury)

#### INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including the medicine you can buy without a prescription, natural health products, vitamin or mineral supplements.

**Drugs that may interact with ZEMPLAR® Injection USP include:**

- Products containing phosphate or vitamin D.
- Products which contain aluminum or magnesium, these would include antacids (stomach medicine) or phosphate binders (used to remove phosphate from the blood).
- Digitalis compound e.g., digoxin or digitoxin (medicines used in certain heart conditions), thiazide diuretics (a type of water tablet) or medicines which contain high levels of calcium.
- Products used to treat fungal infections (e.g., ketoconazole).

#### PROPER USE OF THIS MEDICATION

##### Usual dose:

The dosage of ZEMPLAR® Injection USP varies for each patient. Your doctor will decide on the appropriate dose for you. ZEMPLAR® Injection USP will be injected into your vein through the hemodialysis line. You should not receive ZEMPLAR® Injection USP any more frequently than every other day during dialysis.

##### Overdose:

If you think you are given too much ZEMPLAR® Injection USP than you should, talk to your nurse, doctor, or contact an emergency room of the nearest hospital.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

The most common side effects experienced: *These might affect between 1 and 10 in every 100 people.* High blood levels of calcium and phosphate; parathyroid disorder; itchy skin and a change in your sense of taste.

Uncommon side effects: *These might affect less than 1 in every 100 people.* Blood disorders; enlargement of lymph nodes; taking longer for your blood to clot; blood pressure problems; irregular heart beat; heart attack; stroke; fainting; tissue swelling; fluid retention; loss of appetite; weight loss; constipation; dry mouth; feeling thirsty; diarrhea; feeling sick; vomiting; bleeding from your bottom; difficulty swallowing; indigestion. The results of blood tests may show raised liver enzymes. Unsteadiness; confusion; sleep disturbance; feeling anxious; dizziness; behavioural disorders; shaking; muscle twitches; numbness; eye (glaucoma); breathing difficulties; cough; nose bleeds; fluid on the lungs; chest infection; asthma; sore throat; rash; altered hair growth; sweating; feeling tired; joint pain; muscle pain; twitching; breast cancer; breast pain; impotence; inflammation of vagina; allergic reaction; aches and pains; feeling tired; fever; pain around the injection site; infections; flu-like symptoms, swelling of the face and mouth.

Too much ZEMPLAR® Injection USP can cause hypercalcemia (higher than normal levels of calcium in the blood, which can be harmful). To help prevent this your blood will be tested frequently early in your treatment, so that your doctor can adjust the dose of ZEMPLAR® Injection USP to suit you.

Early signs and symptoms of hypercalcemia associate with vitamin D overdose include weakness, headache, feeling sleepy or sick, vomiting, dry mouth, constipation, muscle pain, bone pain and metallic taste.

Symptoms of hypercalcemia associated with vitamin D overdose which may develop over a longer period include a lack of appetite, feeling sleepy, weight loss, sore eyes, runny nose, itchy skin, feeling hot and feverish, decreased sex drive, calcium deposits and severe abdominal pain (due to an inflamed pancreas).

The results of blood and urine tests may show high cholesterol, urea nitrogen (BUN) and raised levels of liver enzymes. Your blood pressure may be affected and heart beat irregularities can occur. ZEMPLAR® Injection USP may rarely cause mental changes including confusion, drowsiness, insomnia or nervousness.

**If you experience any other unusual or unexpected symptoms while receiving ZEMPLAR® Injection USP tell 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
		Only if severe	In all cases	
Uncommon	Back pain		T	
	Fever		T	
	Headache	T		
	Heart attack		T	
	High blood pressure		T	
	Irregular heart beat		T	T
	Stroke		T	
	Gastrointestinal disorder (diarrhea, abdominal pain, low blood flow to the intestine)		T	
	Nausea		T	
	Rectal bleeding		T	
	Vomiting		T	
	Confusion		T	T
	Dizziness		T	T
	Impaired thinking (Not thinking clearly)		T	
	Asthma (wheezing)		T	
	Increased cough	T		
Shortness of breath		T		

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

**HOW TO STORE IT**

ZEMPLAR® Injection USP should be stored between 15 and 25°C. Protect from light, freezing and excessive heat.

### **REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: [cadrmpp@hc-sc.gc.ca](mailto:cadrmpp@hc-sc.gc.ca)

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness

Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

*NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.*

### **MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.abbott.ca> or by contacting the sponsor, Abbott Laboratories, Limited at 1-800-699-9948.

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