

CONSUMER INFORMATION
Product Monograph Part III

ZEMPLAR*
Paricalcitol
5 mcg/mL, solution

Abbott Laboratories Ltd.

Submission Control No. 087818

The Consumer Information Section (Part III) of the Product Monograph for ZEMPLAR* has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on March 31, 2005 and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

PART III: CONSUMER INFORMATION**ZEMPLAR*
Paricalcitol Injection USP**

This leaflet is part III of a three-part "Product Monograph" published when ZEMPLAR* 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*. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for and what it does:**

ZEMPLAR* is a synthetic vitamin D analogue. 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.

ZEMPLAR* is used to replace the body's naturally produced active form of vitamin D.

ZEMPLAR* is used in hemodialysis patients for the prevention and treatment of secondary hyperparathyroidism (high levels of parathyroid hormone which can cause bone problems) associated with chronic renal failure (long term kidney failure).

When it should not be used:

ZEMPLAR* 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. Each 1ml of ZEMPLAR* injection contains 5 micrograms of paricalcitol.

What the important nonmedicinal ingredients are:

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

What dosage forms it comes in:

ZEMPLAR* is available in ampoule or Flip-top vials as follows:

- 5 ampoules containing 1 mL or 2 mL each
- 25 Flip-top vials containing 1 mL or 2 mL each
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WARNINGS AND PRECAUTIONS

This product contains 20% ethanol. The amount of ZEMPLAR* 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* 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 allergies to this ZEMPLAR* or any of its ingredients or components of the container.
- You take (or have recently taken) any other medicines.

Remember to mention medicines you bought yourself without a prescription, over the counter, like herbal products, natural products, vitamins and minerals.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with ZEMPLAR* 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.

PROPER USE OF THIS MEDICATION**Usual dose:**

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

Discard any unused product.

Overdose:

Too much ZEMPLAR* can cause very high levels of calcium in the blood, which can be harmful. To help prevent this your blood will be tested frequently, e.g. twice a week, early in your treatment, so that your doctor can adjust the dose of ZEMPLAR* to suit you.

Symptoms, which could appear soon after being given too much ZEMPLAR*, include weakness, headache, feeling sleepy or sick, vomiting, dry mouth, constipation, muscle pain, bone pain and metallic taste.

Symptoms 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* may rarely cause mental changes including confusion, drowsiness, insomnia or nervousness.

If you experience any of these side effects inform your doctor immediately.

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.*

Heart, blood and circulation: 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 and fluid retention.

Digestive system: Loss of appetite; weight loss; constipation; dry mouth; feeling thirsty; diarrhoea; feeling sick; vomiting; bleeding from your bottom; difficulty swallowing; indigestion. The results of blood tests may show raised liver enzymes.

Nervous system: Unsteadiness; confusion; sleep disturbance; feeling anxious; dizziness; behavioural disorders; shaking; muscle twitches; numbness; eye (glaucoma).

Respiratory System: Breathing difficulties; cough; nose bleeds; fluid on the lungs; chest infection; asthma; sore throat

Skin: Rash; altered hair growth; sweating.

Muscles and Bones: Feeling tired; joint pain; muscle pain; twitching.

Reproductive organs: Breast cancer; breast pain; impotence; inflammation of vagina.

Others: Allergic reaction; aches and pains; feeling tired; fever; pain around the injection site; infections; flu-like symptoms, swelling of the face and mouth.

If you experience any other unusual or unexpected symptoms while receiving ZEMPLAR* 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			
Whole Body • back pain • fever • headache	✓	✓ ✓	
Heart, blood and circulation • heart attack • high blood pressure • irregular heart beat • stroke		✓ ✓ ✓ ✓	✓
Digestive System • stomach disorder • nausea • rectal bleeding • vomiting		✓ ✓ ✓ ✓	
Nervous System • confusion • dizziness • impaired thinking		✓ ✓ ✓	✓ ✓
Respiratory System • asthma • increased cough • shortness of breath	✓	✓ ✓	

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

GENERAL ADVICE ABOUT PRESCRIPTION MEDICINES:

Talk to your doctor or other health care provider if you have any questions about this medicine or your condition. If you have any concerns about this medicine, ask your doctor. Your doctor or pharmacist can give you information about this medicine that was written for health care professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people.

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: cadtmp@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

Additional information can be found at:

<http://www.abbott.ca>

or by contacting the sponsor, Abbott Laboratories, Limited at 1-800-567-2226.

This leaflet was prepared by Abbott Laboratories, Limited.

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