

## PART III: CONSUMER INFORMATION

### Pr CALCIJEX<sup>®</sup> calcitriol injection

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

#### ABOUT THIS MEDICATION

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

- The management of hypocalcemia (low calcium levels) in patients undergoing chronic renal dialysis.

##### What it does:

CALCIJEX<sup>®</sup> helps to regulate calcium levels in the blood.

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

You should not use CALCIJEX<sup>®</sup> if you:

- are allergic to calcitriol, or vitamin D or its analogues and derivatives, or any of the non-medicinal ingredients in CALCIJEX<sup>®</sup>
- have high calcium levels (hypercalcemia)
- have high vitamin D levels (vitamin D toxicity).

##### What the medicinal ingredient is:

calcitriol

##### What the important non-medicinal ingredients are:

Anhydrous dibasic sodium phosphate, edentate disodium, monobasic sodium phosphate monohydrate, polysorbate 20, sodium ascorbate, sodium chloride.

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

CALCIJEX<sup>®</sup> is supplied in 1 mL ampoules containing 1 mcg or 2 mcg of calcitriol.

#### WARNINGS AND PRECAUTIONS

**BEFORE you use CALCIJEX<sup>®</sup> talk to your doctor or pharmacist if:**

- you are allergic to vitamin D or to any ingredient of CALCIJEX<sup>®</sup>
- you are on digitalis
- you are pregnant or nursing
- you are taking other vitamin D product or its derivatives.

The safety and effectiveness of CALCIJEX<sup>®</sup> in children under 18 years of age have not been established.

#### INTERACTIONS WITH THIS MEDICATION

**Drugs that may interact with CALCIJEX<sup>®</sup> include:**

- digitalis
- anti-seizure medications (e.g., diphenylhydantoin and barbiturates)
- antacids containing magnesium
- corticosteroids
- thiazide diuretics (e.g., hydrochlorothiazide)

#### PROPER USE OF THIS MEDICATION

The effectiveness of CALCIJEX<sup>®</sup> therapy is based on the assumption that each patient is receiving an adequate daily intake of calcium.

To ensure that each patient receives an adequate daily intake of calcium, the physician may either prescribe a calcium supplement or instruct the patient in appropriate dietary measures.

##### Usual dose:

The dose will be decided by your doctor and be given through a catheter three times per week at the end of hemodialysis. You should also take your prescribed daily dose of calcium and follow the instructions on diet and supplement intake.

##### Overdose:

If you think you have been given more CALCIJEX<sup>®</sup> than you should have, talk to your doctor or nurse or contact a poison control center.

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

The most common side effect of CALCIJEX<sup>®</sup> is hypercalcemia (high calcium levels).

Early symptoms (within first few months of use of drug) of hypercalcemia and vitamin D toxicity include: weakness, headache, feeling sleepy, nausea, irregular heart beat, excessive thirst, vomiting, dry mouth, constipation, abdominal pain, loss of appetite, discomfort or unpleasant sensation in the upper abdomen, muscle pain, bone pain, and metallic taste.

Late symptoms (with continued [chronic] use of drug): too much protein in your urine, loss of appetite, feeling indifferent or lack of emotion, abnormal heart beat, swelling or infection near your eyelid, decreased sex drive, loss of water/not enough water in your body, abnormal changes in bone and muscle development, deposit of calcium salt in tissues, excessive nitrogen in your urine,

elevated liver function tests, high cholesterol, high blood pressure, feeling too hot, too much calcium in your kidneys, needing to urinate at night, inflammation of the pancreas, sensitivity to light, excessive thirst, increased need to urinate, itching, loss of contact with reality, runny nose, changes in sensation such as pain, touch, pressure and temperature sensation, urinary tract infections, and weight loss.

If these side effects do not go away or if you experience other side effects which are not listed above, talk to your doctor right away.

### HOW TO STORE IT

Store between 15 and 25°C. Protect from light.

### 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 on line at:**  
[www.healthcanada.gc.ca/medeffect](http://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**
  - **Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701C  
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 <http://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.abbott.ca>  
or by contacting the sponsor, Abbott Laboratories, Limited, Saint-Laurent, Qc H4S 1Z1 at:  
1-800-699-9948

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### 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	elevated blood calcium		✓
Uncommon	allergic reactions such as:		✓
	- hives		✓
	- difficulty breathing		✓
	- rapid drop in blood pressure		✓
	dehydration such as:		✓
	- light-headedness		✓
	- dizziness		✓
	- weakness		✓
	- dry mouth		✓
	- increased thirst		✓
- decreased production of urine		✓	

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