

PART III: CONSUMER INFORMATION

Pr MYLAN-CINACALCET

Cinacalcet Tablets
30 mg, 60 mg, 90 mg

Cinacalcet (as cinacalcet hydrochloride)

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

ABOUT THIS MEDICATION

What the medication is used for:

MYLAN-CINACALCET is used:

- to treat secondary hyperparathyroidism (high-per-pear-uh-THIGH-royd-izm) in patients with chronic kidney disease (CKD) receiving dialysis;
- to reduce high levels of calcium in the blood (hypercalcemia) in patients with parathyroid cancer;
- to reduce high levels of calcium in the blood (hypercalcemia) in patients with primary hyperparathyroidism when removal of the gland(s) is not possible.

What it does:

Four small glands located behind the thyroid gland in your neck are called parathyroid glands. They make a hormone called parathyroid hormone (PTH). Normally, PTH makes sure you have just enough calcium and phosphorus in your blood to keep your bones, heart, muscles, nerves and blood vessels working well.

Secondary hyperparathyroidism

When your kidneys are working, PTH keeps your calcium and phosphorus levels normal by moving the right amounts of calcium and phosphorus in and out of your bones. Chronic Kidney Disease (CKD) can cause a condition called secondary hyperparathyroidism.

When your kidneys aren't working properly, the calcium and phosphorus balance in your body is upset, and your parathyroid glands send out too much PTH to your body. This can cause bone disease and also may be a risk factor for heart disease and abnormal calcification of blood vessels and other parts of the body. MYLAN-CINACALCET treats secondary hyperparathyroidism by lowering PTH. This helps keep calcium and phosphorus within proper levels.

Parathyroid carcinoma/Primary hyperparathyroidism

Primary hyperparathyroidism is caused by an overactive, enlarged parathyroid gland (or glands), occasionally due to cancer of the parathyroid gland. In primary hyperparathyroidism, your parathyroid glands send out too much PTH to your body and your blood level of calcium becomes high. MYLAN-CINACALCET lowers PTH by telling your parathyroid glands to stop releasing too much PTH into your blood. This helps lower your blood calcium levels.

When it should not be used:

You should not take MYLAN-CINACALCET if you are hypersensitive (allergic) to any of the ingredients in the tablet.

You should not take MYLAN-CINACALCET if your blood calcium level is below the normal range.

What the medicinal ingredient is:

Cinacalcet hydrochloride

What the important nonmedicinal ingredients are:

Colloidal anhydrous silica, crospovidone, magnesium stearate, microcrystalline cellulose and povidone.

Tablet coating: FD&C Blue No. 2, hydroxypropyl methylcellulose, iron oxide yellow, titanium dioxide and triacetin.

What dosage forms it comes in:

MYLAN-CINACALCET is available as small, light green tablets packaged in bottles of 30 and 100 tablets. Each tablet contains 30 mg, 60 mg, or 90 mg of cinacalcet (as cinacalcet hydrochloride).

WARNINGS AND PRECAUTIONS

BEFORE you use MYLAN-CINACALCET talk to your doctor or pharmacist if:

1. You have or had seizures (convulsions). The risk of having a seizure is greater if you have had seizures before.
2. You have or had heart problems (low blood pressure or worsening heart failure).
3. You have or had liver problems.
4. You have lower blood calcium levels.
5. You are pregnant, breastfeeding, or plan to do so.

Low calcium levels can have an effect on your heart rhythm. Tell your doctor if you experience an unusually fast or pounding heart beat, if you have heart rhythm problems, or if you take medicines

known to cause heart rhythm problems, while taking MYLAN-CINACALCET.

MYLAN-CINACALCET is not recommended for patients with CKD not receiving dialysis.

MYLAN-CINACALCET should not be used in children. A death was reported in an adolescent clinical trial patient with very low calcium levels in the blood (hypocalcemia).

INTERACTIONS WITH THIS MEDICATION

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Drugs that may interact with MYLAN-CINACALCET include: ketoconazole, erythromycin, itraconazole, metoprolol, flecainide, vinblastine, thioridazine, rifampin, phenytoin, or medicines such as tricyclic antidepressants (desipramine, amitriptyline).

PROPER USE OF THIS MEDICATION

It is important to take MYLAN-CINACALCET exactly as your doctor has instructed you. Your doctor will tell you how much MYLAN-CINACALCET to take. Your doctor will order regular blood tests to measure how you are responding to MYLAN-CINACALCET and may increase or decrease your dose based on your PTH, calcium, and phosphate levels.

Usual Adult Dose:

If you have secondary hyperparathyroidism the usual starting dose for MYLAN-CINACALCET is one 30 mg tablet once daily.

If you have parathyroid cancer or primary hyperparathyroidism, the usual starting dose for MYLAN-CINACALCET is one 30 mg tablet twice daily.

MYLAN-CINACALCET is taken with food or right after a meal. MYLAN-CINACALCET tablets must be taken whole and are not to be chewed, crushed, or divided. It's best to take MYLAN-CINACALCET at the same time each day.

MYLAN-CINACALCET can be used alone or in combination with vitamin D sterols and/or phosphate binders.

Overdose:

Tell your doctor or contact your regional Poison Control Centre immediately if you think you took more than the recommended dose of MYLAN-CINACALCET.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Do not take a double dose to make up for forgotten daily doses. If you have forgotten a dose of MYLAN-CINACALCET, you should take your next daily dose as normal.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

All medicines have side effects.

If you have any of the following side effects while taking MYLAN-CINACALCET, you should tell your doctor right away.

- Nausea and vomiting. These are the most common side effects seen with MYLAN-CINACALCET treatment. This may make it difficult to take your medicines.
- Diarrhea, muscle pain and back pain. These side effects also are commonly reported.
- Rash or hypersensitivity (allergic reactions). Cases of rash have been commonly reported, while cases of hypersensitivity (allergic reactions) have been uncommonly reported.
- Hives (urticaria) is very rarely reported.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema) is also very rarely reported.
- Joint pain (pseudogout)

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 | Diarrhea | √ | |
| | Hypocalcemia/ low calcium level (symptoms may include: unusually fast or pounding heart beat, numbness/ tingling around mouth, muscle aches/cramps, seizures) | | √ |

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 | Seizures (convulsions) | | √ |
| | Hypersensitivity/allergic reactions (symptoms may include: skin rash, hives, itching, difficulty breathing, swelling of face, tongue or throat) | | √ |
| Very Rare | Low blood pressure (symptoms may include: dizziness, feeling lightheaded, feeling tired) | | √ |
| | Worsening heart failure (symptoms may include: increased difficulty breathing, swelling of the legs, ankles and feet, feeling more tired) | | √ |
| | Angioedema (swelling of the face, lips, mouth, tongue or throat) | | √ |
| | Severe hypersensitivity/allergic reactions (symptoms may include: skin rash, hives, itching, difficulty breathing or swallowing, swelling of face, tongue or throat) | | √ |

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

HOW TO STORE IT

Store MYLAN-CINACALCET tablets at room temperature (15°C to 30°C). Keep in a safe place out of the reach and sight of children.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mpps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

Note: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document can be found at: www.mylan.ca.

The full Product Monograph prepared for health professionals can be obtained by contacting the sponsor, Mylan Pharmaceuticals ULC at: 1-844-596-9526

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