

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Pr **CYTOMEL**[®] (Liothyronine Sodium Tablets)

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

ABOUT THIS MEDICATION

What the medication is used for

Cytomel[®] (liothyronine sodium) is used for the treatment of:

- Mild to severe hypothyroidism (thyroid gland does not produce enough hormone);
- Enlarged thyroid gland (simple goiter)

What it does

Cytomel[®] (liothyronine sodium) is a synthetic form of a hormone produced by the thyroid gland called triiodothyronine.

When it should not be used

Cytomel[®] should not be used if you have:

- a hypersensitivity or allergy to thyroid hormones (liothyronine sodium) or to any non medicinal ingredients in Cytomel[®];
- uncorrected adrenal gland under-activity;
- acute myocardial infarction (heart attack)

What the medicinal ingredient is

Liothyronine sodium

What the non medicinal ingredients are

Calcium sulfate, gelatin, starch (corn), stearic acid, sugar and talc

What dosage form it comes in

Cytomel[®] is available as round, white to off-white tablets. The tablets are available in two strengths: 5 micrograms and 25 micrograms. The 5 microgram has the letters KPI on one side and 115 on the other. The 25 microgram has the letters KPI 116 on one side and a single bisect on the other.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Cytomel[®], like other thyroid hormones, should not be used for the treatment of obesity or for weight loss, either alone or with other medicines. At normal doses, Cytomel[®] does not reduce body weight and at higher doses, it can produce serious or even life-threatening side effects.

BEFORE or WHILE YOU USE CYTOMEL[®], talk to your doctor if you have the following condition:

- any heart problems, such as a heart attack, angina pectoris (chest pain)
- a history problem with thyroid (myxedema), or adrenal or pituitary gland
- kidney disease
- high blood sugar (diabetes)
- decreased development of sexual organs (hypogonadism)
- bone thinning (osteoporosis)
- pregnant or planning to become pregnant
- breast feeding
- blood clotting problem

INTERACTIONS WITH THIS MEDICATION

Before or while you use Cytomel[®] tell your doctor or pharmacist about all other medications you take including medications that you bought without a prescription, vitamins, and natural products. Particularly if you are taking the following:

- Blood thinner (anticoagulants)
- Medications for high cholesterol levels such as lovastatin, cholestyramine, clofibrate
- Medications for high blood sugar or insulin
- Medications that contain estrogen such as birth control pills
- Amiodarone
- Medicines that contain iodine such as radiographic contrast agents
- Heroin/methadone
- 5-fluorouracil, mitotane, tamoxifen
- Tricyclic antidepressant such as imipramine
- Digoxin (digitalis)
- Cyokines such as interferon-alpha, interleukin-2
- Growth hormones
- Ketamine
- Theophylline
- Diazepam
- Ethionamide
- Metoclopramide
- Perphanazine
- Resorcinol (topical products)
- Para-aminosalicylate sodium

Some medicines may interfere with blood tests done to

determine thyroid hormone levels (thyroid function tests). It is important to inform your doctor of all medicines you are taking before and at the time of blood tests.

The following drugs are known to interfere with laboratory tests performed in patients on thyroid hormone therapy:

- Androgens (male hormones)
- Corticosteroids (eg., prednisone, dexamethasone)
- Estrogens and estrogen-containing oral contraceptives (birth control pills)
- Preparations containing iodine
- Salicylates (eg., aspirin)

PROPER USE OF THIS MEDICATION

You should take Cytomel[®] as prescribed by your doctor. Treatment is usually started with a low dose of Cytomel[®], then increased gradually according to your response.

Overdose

In case of drug overdose, contact your doctor or a Poison Control Centre, or go to the emergency room of the hospital near you immediately, even if there are no symptoms.

Missed dose

If you miss a dose, take it as soon as you remember on the same day. Skip that dose if you do not remember until the next day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects with Cytomel[®] may include symptoms of hyperthyroidism as follows: Headache, excessive sweating, fatigue, increased appetite, weight loss, fever, nervousness, anxiety, irritability, insomnia, cardiac arrhythmias (heartbeats which are irregular or too fast), angina pectoris (chest pain), diarrhea and menstrual irregularities.

Tell your doctor about any other side effect that is not included above or if you have any question. Your doctor may ask you stop taking Cytomel[®] until the symptoms disappear, and re-start after one or two days at a lower dose.

HOW TO STORE IT

Store at room temperature (15-25°C or 59-77°F), away from heat, light and moisture.

Keep container firmly closed and away from the reach of children.

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 0701D
Ottawa, Ontario
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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada Inc., at:
1-800-463-6001.

This leaflet was prepared by Pfizer Canada Inc.

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