



THALIDOMIDE

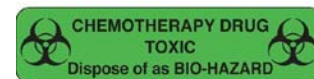
INSTRUCTIONS FOR THE PHARMACIST

Prescription

- All orders should be written on a **pre-printed order**; if not, compare prescription to standard regimens in the Systemic Therapy Manual to confirm the dosing and instructions
 - The order must be signed by BOTH the prescriber (at the bottom) AND at least one other oncology health professional (nurse or hospital pharmacist) who has verified the order
- The prescription may **not** be refilled (unless specifically ordered by the oncologist) and it may **not** be filled as a continuing care prescription
 - If the prescriber has written for refills, do **not** dispense until the oncology team authorizes the refill.
 - Blood work must be checked for each cycle.
- Always check for drug-drug interactions, especially before the first cycle, as described below. Consult the **Drug Interactions** section (page 4), and consider an online drug interactions checking program.
- Check with patient for any other medications filled at a different pharmacy

Handling and Dispensing

- When handling this drug, disposable gloves should be worn at all times by any woman of child-bearing potential. Counting trays and other equipment directly exposed to the drug should be cleaned with **soap and water**, followed by rinsing with copious amounts of water (wear gloves).
- Do not open capsules in an open air environment and risk inhalation of powder.
- ALWAYS affix the auxiliary label to identify this medication as “Cancer Chemotherapy”- this is an important warning label for other health professionals caring for the patient.



Patient Counseling and Follow-up

- Counsel the patient, including the key messages listed below. Use the **Initial Assessment and Patient Counseling Visit- Pharmacist Guide** ① and the **Medication Info Sheet** ② for this drug. Be sure that you know the specific treatment schedule and that this is clearly communicated to the patient.
- Call the patient within the first week to identify any problems with adverse reactions or adherence.
 - When speaking with the patient and during call backs, ask the patient to identify any problems with medication adherence. Use the **First Follow-Up Call/Visit- Pharmacist_Guide** ①.
- Continuing follow up calls between clinic visits are necessary for ADR identification and prevention and for adherence management. Contact the oncology clinic nurse or hospital pharmacist to negotiate who will do follow-up calls between clinic visits. Tell the patient that you plan to call back to check on their progress. Consider the suggested call-back schedule (pg. 2), with specific questions for each contact.
 - When speaking with the patient and during call backs, ask the patient to identify any problems with medication adherence. Use the **Continuing Follow-Up Calls/Visits - Pharmacist_Guide** ①.
- If the patient reports any adverse effects, consider the management strategies suggested in the **Adverse Drug Reaction Management Guide** ②.
- ALWAYS document your findings in the patient profile of your pharmacy computer system
- ALWAYS contact the patient’s cancer care team of any findings and actions you have taken.
- ALWAYS **watch for any unusual or unexpected symptoms or problems** (such as an adverse reaction that appears too soon or too severe) and contact the cancer care team promptly if something seems wrong with the patient experience.



CLINICAL INDICATIONS

Thalidomide is clinically indicated for:



- Multiple myeloma

DRUG ADMINISTRATION

- Thalidomide may be taken **once daily** at the same time each day, with or without food. Taking the capsules at bedtime may help to prevent somnolence (at least 1 hour after evening meal).
- Capsules should be swallowed whole with a glass of water. Do not open or chew capsules.
- Keep capsules in blister pack until time of ingestion.
- Keep capsules out of reach of children and protect from light.
- If a dose is missed, do not take a double dose the next day to make up for it.

PATIENT COUNSELLING- INITIAL AND FOLLOW-UP CALLS

- In addition to other printed materials, use the **Medication Info Sheet** from the Cancer Care Nova Scotia website, and consider the more detailed suggestions in this toolkit.

	Key Messages
Initial counselling- At time of dispensing	<ul style="list-style-type: none"> • How to take the medication properly (including treatment-free breaks) • When to call back to the cancer care team for urgent care • Use the Initial Assessment and Patient Counseling Visit- Pharmacist Guide ① and the drug-specific Medication Info Sheet ②
First call-back – Within first week: 	<ul style="list-style-type: none"> • Identify any initial problems with understanding or adherence • Use the First Follow-Up Call/Visit- Pharmacist Guide ① and the Medication Info Sheet ② (if needed) • Reinforce initial key messages <ul style="list-style-type: none"> ○ How and when treatment is taken ○ Barriers to adherence- remembering to take medication; reluctance to take treatment; financial issues; nausea, vomiting or other adverse effects; trouble with packaging; felt better off medication; other concerns ○ Suggest strategies to ensure adherence; reminder that full dose is needed for cancer control- partial doses may be ineffective. • Identify any early adverse effect symptoms; suggest management strategies
Second call-back – After 2-3 weeks: (telephone or return visit to Pharmacy) 	<ul style="list-style-type: none"> • Identify any adverse effects (PROBE for evidence of any adverse effects- see below) • Use the Continuing Follow-Up Calls/Visits- Pharmacist Guide ① <ul style="list-style-type: none"> ○ If any identified, contact oncologist or oncology nurse, and consider the information below under Adverse Effects • Ask if there are any pills left over (at end of prescription) and, if so, PROBE to determine any barriers to treatment adherence (see above) • Reinforce initial key messages
Subsequent cycles- (at least one call during each cycle):	<ul style="list-style-type: none"> • Negotiate with patient and cancer care team for ongoing needs for counseling and timely follow up calls • Use the Continuing Follow-Up Calls/Visits- Pharmacist Guide ① • Adherence assessment and support is an important issue for reinforcement at each visit and mid-cycle call-back as treatment continues

ADVERSE EFFECTS: PREVENTION AND MANAGEMENT SUGGESTIONS

If you identify any of the following, you should contact the oncologist and tell the patient to call the oncologist or go directly to the Emergency Department of the nearest hospital right away **↗** :

- Signs of allergic reaction (hives, trouble breathing, swollen face, lips, tongue, or throat.
- Signs of infection (fever, chills, body aches, symptoms of the flu)
- Symptoms of deep vein thrombosis (pain or swelling in arm, thigh, or calf)
- Bradycardia (slow heart rate, shallow breathing, feeling as though he/she may pass out)
- Stevens-Johnson syndrome (red, raised skin rash (especially with fever, fast heart rate, and dizziness or fainting)
- Seizure

The following are the common adverse effects from Thalidomide.

<p>More Common</p> <p><u>CNS disorders</u></p> <ul style="list-style-type: none"> • Fatigue★, somnolence◆, dizziness◆, peripheral neuropathy◆ <p><u>Gastrointestinal disorders</u></p> <ul style="list-style-type: none"> • Constipation★ <p><u>Neuromuscular disorders</u></p> <ul style="list-style-type: none"> • Tremor◆ <p><u>General disorders</u></p> <ul style="list-style-type: none"> • Peripheral edema◆ • Asthenia★ 	<p>Less Common</p> <p><u>Endocrine & Metabolic disorders</u></p> <ul style="list-style-type: none"> • Hypocalcemia◆, hyperlipemia◆ <p><u>Hematologic disorders</u></p> <ul style="list-style-type: none"> • Myelosuppression★ (<i>may be due to other drugs given with thalidomide</i>): anemia, leukopenia, neutropenia, thrombocytopenia <p><u>Gastrointestinal disorders</u></p> <ul style="list-style-type: none"> • Nausea★, anorexia, weight loss • Weight gain, diarrhea★, oral moniliasis◆ • Dry mouth★, gas★, tooth pain★ <p><u>Genitourinary disorders</u></p> <ul style="list-style-type: none"> • Impotence◆ <p><u>Neuromuscular & Skeletal disorders</u></p> <ul style="list-style-type: none"> • Muscle weakness◆, myalgia★ • Paresthesia◆, arthralgia★ • Back pain★, neck pain★ or rigidity <p><u>Respiratory disorders</u></p> <ul style="list-style-type: none"> • Pharyngitis◆, rhinitis◆, sinusitis◆ <p><u>General disorders</u></p> <ul style="list-style-type: none"> • Blood in urine◆ • Trouble breathing↗ • Diaphoresis • Infection↗
<p>Less Common</p> <p><u>Cardiovascular disorders</u></p> <ul style="list-style-type: none"> • Edema, thrombosis/embolism↗, hypotension, bradycardia↗ <p><u>CNS disorders</u></p> <ul style="list-style-type: none"> • Insomnia◆, nervousness, malaise, confusion◆, anxiety/agitation◆ • Motor neuropathy◆, headache★ • Vertigo†, pain★ • Seizure↗ <p><u>Dermatologic disorders</u></p> <ul style="list-style-type: none"> • Rash◇, peeling skin†, dry skin★, acne • Maculopapular rash★ • Dermatitis★, itchy skin★, nail disorder • Stevens-Johnson syndrome↗ 	

★ For detailed recommendations on the management of these adverse drug reactions, see the **Adverse Drug Reaction Management Guide** ②

◆ For management of these symptoms, the patient should see his physician

↗ These symptoms require urgent attention- advise the patient to go to the Emergency Department or contact their doctor (see instructions above)

DRUG INTERACTIONS

Take a **thorough medication history** (call other pharmacies if necessary) and determine the potential for all other drugs to increase or decrease Thalidomide plasma concentration.

- Drug interactions are often missed by community pharmacy computer systems
- **REPORT any potential interaction** to the prescribing oncologist- either the SUNItinib or the interaction drug may need to be dose altered or discontinued.



It is strongly recommended that you check any concurrent medications for interactions with this oral chemotherapy agent. Try one of the following comprehensive programs for checking drug interactions.

Online Programs for Drug Interaction Checking-Publicly available:

- http://www.drugs.com/drug_interactions.php
- <http://reference.medscape.com/drug-interactionchecker>
- <http://www.healthline.com/druginteractions>
- <http://cpref.goldstandard.com/inter.asp?r=8084>
- <http://umm.edu/health/medical/drug-interaction-tool>
- <http://online.epocrates.com/> (free account required)

Other Interaction Checkers- Subscription required:

- Lexicomp
- Micromedex
- eCPS

Some common interactions with Thalidomide are:

- Azelastine (nasal): may increase CNS depressant effect of Azelastine (*avoid combination*)
- Buprenorphine: may increase CNS depressant effect of Buprenorphine
- CloZAPine: may increase the toxicity of Clozapine (specifically, agranulocytosis). *Avoid combination.*
- CNS depressants: may increase the toxicity of Thalidomide. Consider dose reduction of CNS depressants (opioids, barbiturates) with concomitant use.
- Dexamethasone (systemic): may increase the dermatologic and thrombogenic adverse effects of Thalidomide
- Doxylamine, Droperidol, HydrOXYzine, Magnesium sulfate: may increase the CNS depressant effect of Thalidomide.
- Leflunomide: may increase toxicity of Leflunomide (specifically, the risk of hematologic toxicity). Consider not using a leflunomide loading dose in patients receiving Thalidomide. Monitor patient for bone marrow suppression at least monthly if using these drugs concurrently.
- Methotrimprazine: Thalidomide may increase CNS depressant effect of Methotrimprazine and vice versa.
- Metyrosine, Pramipexole, ROPINIRole, Rotigotine: Thalidomide may increase the sedative effect of these drugs
- Mirtazapine, Paraldehyde: Thalidomide may increase CNS depressant effect of these drugs
- Pamidronate: may increase nephrotoxic effect of Pamidronate
- SSRIs: may increase toxicity of SSRIs, specifically, the risk of psychomotor impairment may be increased.
- Tacrolimus (topical): may increase the toxicity of Thalidomide (*avoid combination*)
- Vaccines (inactivated, live): may increase toxicity and decrease therapeutic effect of vaccines (*avoid combination*)
- Zoledronic acid: may increase toxicity of Zoledronic acid
- Zolpidem: may increase CNS depressant effect of Zolpidem.

Note: Drinking alcohol while taking Thalidomide may increase CNS depression. Caution patients about effects and monitor for increased effects when patients drink alcohol while taking this medication.

Cat's claw and Echinacea should be avoided while taking Thalidomide.