1 thalidomide (tha-lid-oh-mide)

Thalidomide

Classification: immunosuppressants

Indications
Cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). Prevention (maintenance) and suppression of recurrent ENL. Newly diagnosed multiple myeloma (with dexamethasone).

Precautions
Hypersensitivity; OB: Women with childbearing potential (unless specific conditions are met); OB: Pregnancy (can cause fetal harm); Seizure disorders; Sexually mature men (unless specific conditions are met); Lactation: Potential for serious adverse reactions in the infant.

Dosage
Cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL): PO (Adults/Children). 100–300 mg/day initially; up to 400 mg/day has been used, depending on previous response. Every 3–6 mo, attempts should be made to taper and discontinue in decrements of 50 mg q 2–4 wk.

Multiple Myeloma: PO (Adults): 200 mg daily in 28-day treatment cycles. Dexamethasone 40 mg is administered on Days 1–4, 9–12, 17–20.

NURSING IMPLICATIONS
Assessment
Monitor monthly for initial 1 mo and periodically during therapy to detect early signs of peripheral neuropathy (numbness, tingling, or pain in hands and feet). Commonly occurs with prolonged therapy, but has occurred following short-term use or following completion of therapy. May be severe and irreversible. Electrophysiologic testing may be done at baseline and every 6 mo to detect asymptomatic changes. Discontinue if symptoms develop.

Adverse Reactions/Side Effects

Interactions
Drug-Drug: CNS depression with concurrent use of barbiturates, sedative/hypnotics, alcohol, chlorpromazine, reserpine, or other CNS depressants. Concurrent use of agents that may cause peripheral neuropathy risk of peripheral neuropathy.

Drug-Natural Products: Concommitant use with echinacea, and melatonin may interfere with immunosuppression.
Peripheral neuropathy. If symptoms occur, discontinue thalidomide immediately to limit further damage. Reinitiate therapy only if neuropathy returns to baseline.

- Monitor for signs of hypersensitivity reaction (erythematous macular rash, fever, tachycardia, hypotension). May require discontinuation of therapy if severe. Reinitiate therapy only if neuropathy returns to baseline.
- Monitor for side effects (constipation, oversedation, peripheral neuropathy); may require discontinuation or dose reduction until side effects resolve.
- Multiple Myeloma: Assess for venous thromboembolism (dyspnea, chest pain, arm or leg swelling) periodically during therapy, especially in patients concurrently taking dexamethasone. Consider prophylaxis depending on patient risk factors.
- Lab Test Considerations: Monitor CBC with differential during therapy. May cause WBC decline; if ANC <750/mm³, consider discontinuing therapy.
- May cause Q viral load levels in patients with HIV.

Potential Nursing Diagnoses

- Impaired skin integrity (indicated by signs of peripheral neuropathy).
- Risk for injury (adverse reactions to thalidomide).

Implementation

- Do not confuse Thalomid (thalidomide) with thiamine.
- Due to teratogenic effects, thalidomide may be prescribed only by prescribers registered in the System for Thalidomide Education and Prescribing Safety (STEPS) program. Thalidomide is started within 24 hr of a negative pregnancy test with a sensitivity of at least 50 mIU/mL. Pregnancy testing must occur weekly during first month of therapy, then monthly thereafter in women with a regular menstrual cycle. For women with irregular menses, pregnancy testing should occur every 2 wk. If pregnancy occurs, thalidomide should be discontinued immediately. Any suspected fetal exposure must be reported to the FDA and the manufacturer, and patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity.
- PO: Administer once daily with water, preferably at bedtime and at least 1 hr after the evening meal. If divided doses are used, administer at least 1 hr after meals.

Patient/Family Teaching

- Instruct patient to take thalidomide as directed. Do not discontinue without notifying health care professional; dose should be tapered gradually. Explain STEPS program to patient.
- Advise patient thalidomide should not be shared with others.
- Question causes drowsiness or dizziness. Caution patient to avoid driving or other activities requiring alertness until response to medication is known.
- Advise patient to change position slowly to minimize orthostatic hypotension.
- Caution patient to use sunscreen and protective clothing to prevent photosensitivity reactions.
- Instruct patient to donate blood and male patients not to donate sperm while taking thalidomide and for 1 month following discontinuation.
- Advise patient to notify health care professional immediately if pain, numbness, tingling, or burning in hands or feet or shortness of breath, chest pain, swelling of arms or legs occurs.
- Caution patient on the extreme importance of maintaining contraception for 1 mo prior to, during, and for 1 mo following discontinuation of therapy. Free Nations of childbearing or use of two methods of reliable contraception must be used unless complete abstinence is used. For men, a latex condom must be used, even if a successful vasectomy has been performed. Patients must meet all of the STEPS conditions. Understands and can follow instructions and is capable of complying with contraceptive measures, pregnancy testing, patient registration, and patient survey. Patients must receive verbal and written warnings of the potential teratogenicity of thalidomide and must acknowledge in writing their understanding and acceptance of these conditions.
- Advise patient to notify health care professional of all Rx or OTC medications, vitamins, or herbal products before taking thalidomide, use appropriate precautions, such as wearing gloves to prevent the potential cutaneous exposure to thalidomide or washing the exposed area with soap and water.

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herbal supplements such as St. John’s Wort with hormonal contraceptive agents may reduce the effectiveness of contraception during and for up to one month after discontinuation of these concomitant therapies. Therefore, women requiring treatment with one or more of these drugs must use two other effective or highly effective methods of contraception or abstain from heterosexual sexual contact while taking thalidomide.

**Evaluation/Desired Outcomes**

- Resolution of the signs and symptoms of active ENL reaction. Usually requires at least 2 wk of therapy; taper medication in 50 mg decrements every 2–4 wk.
- Prevention of recurrent ENL. Tapering off medication should be attempted every 3–6 mo in decrements of 50 mg every 2–4 wk.
- Decrease in serum and urine paraprotein measurements in patients with multiple myeloma.

**Why was this drug prescribed for your patient?**