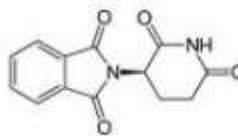


Rx **THALIDOMIDE**
(Thalidomide is an oral medication used for treating the skin conditions of leprosy)



100 % EXPORT QUALITY MEDICINE



GENERIC NAME: thalidomide

DRUG CLASS AND MECHANISM

Thalidomide is an oral medication used for treating the skin conditions of leprosy, a disease caused by a parasite, Mycobacterium leprae. The mechanism of action of thalidomide is not well understood. The immune system reaction to Mycobacterium leprae plays an important role in producing the skin manifestations of leprosy. Scientists believe that thalidomide modifies the reaction of the immune system to Mycobacterium leprae and thereby suppresses the skin reaction. Thalidomide also is being evaluated as a treatment for HIV. Thalidomide was approved by the FDA in July, 1998.

PRESCRIPTION: Yes

PREPARATIONS: Capsules: 50 mg

PRESCRIBED FOR

Thalidomide is used for the treatment and prevention of skin conditions resulting from leprosy and is being evaluated for the management of HIV-related disease. Thalidomide has also been used for treating some autoimmune diseases of the connective tissues including Behcet's disease and skin manifestations of dermatomyositis.

DRUG INTERACTIONS

Tell your doctor of all nonprescription and prescription medication you may use, especially of drugs causing drowsiness such as: barbiturates (e.g., phenobarbital), psychiatric medicine (e.g., chlorpromazine), reserpine, narcotic pain relievers, sedatives, tranquilizers, muscle relaxants, certain antihistamines (e.g., diphenhydramine). Many nonprescription drugs contain antihistamines that cause drowsiness. Check all labels carefully. Consult your pharmacist. Report use of drugs which can cause nerve sensation problems (e.g., didanosine and vincristine). Also report drugs which interfere with birth control pills such as carbamazepine, griseofulvin, modafinil, penicillins, phenytoin, "protease inhibitors" (e.g., indinavir, nelfinavir, saquinavir), rifamycins (e.g., rifampin and rifabutin), St. John's wort. Women who must use one or more of these drugs affecting birth control pills need to use two other effective forms of birth control, or abstain from sexual intercourse. Do not start or stop any medicine without doctor or pharmacist approval.

USES

This medication is used to treat or prevent certain skin conditions related to Hansen's disease (leprosy).

OTHER USES

This drug may also be used for certain conditions in cancer or HIV disease, and other diseases (such as rheumatoid arthritis).

HOW TO USE

This medication must only be used within the S.T.E.P.S. Program (System for Thalidomide Education and Prescribing Safety) guidelines, in order to avoid any possible fetal exposure to the drug. Consult your doctor or pharmacist. Before starting therapy, women of childbearing age should have a pregnancy test within 24 hours before taking the drug. The drug is taken by mouth, generally at bedtime with water and at least one hour after the evening meal as directed. Use this medication exactly as prescribed. Do not increase your dose, use it more frequently or use it for a longer period of time than prescribed because this drug can be habit-forming. Do not suddenly stop taking this medicine. Consult your doctor or pharmacist if you have any questions before using this drug.

SIDE EFFECTS

Drowsiness, dizziness, headache, dry mouth, constipation, loss of appetite or unusual weakness may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Report promptly: tingling or numbness of the hands and feet. Unlikely but report promptly: persistent sore throat, fever, slow or rapid heartbeat, swelling of the hands/feet. Very unlikely but report promptly: unusual bruising, mental or mood changes, chest pain, trouble breathing, calf pain/swelling. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

DOSING

The recommended adult dose is 100-400 mg daily. Thalidomide should be administered in the evening at least one hour after meals and with a full glass of water.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not "double-up" the dose to catch up.

WARNING

Because even a single dose of thalidomide can cause severe birth defects or fetal death, this drug must never be used during pregnancy nor by women who could become pregnant while using this drug. Pregnancy must be ruled out 24 hours before starting therapy with thalidomide. Women must be monitored for pregnancy while using this medication. Patients, physicians, and pharmacists must agree to and comply with the requirements of the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) program developed by the Food and Drug Administration in order to receive this medication. Patients (male or female) who use this medication must use reliable forms of birth control. For males, this means using a latex condom (see Precautions Section). If pregnancy does occur during treatment, contact your doctor immediately.

PRECAUTIONS

Before taking thalidomide, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: nerve disorders (peripheral neuropathy), blood disorders (neutropenia), heart problems (e.g., low blood pressure, slow heartbeat), seizures. Limit alcohol intake, as it may intensify drug side effects. Caution is advised when performing tasks requiring alertness (e.g., driving) as this drug may cause drowsiness. To avoid dizziness and lightheadedness when rising from a seated or lying position, get up slowly. Because thalidomide can cause severe birth defects or fetal death, several precautions are noted below. - Do not donate blood while using thalidomide. - It is unknown if this drug can be absorbed through the skin. Handle the capsules carefully. Caution is advised if you come in contact with the contents of a broken capsule. If this occurs, wash your hands thoroughly with soap and water. - Males - Use a latex condom when having sexual intercourse with a woman during childbearing years, even if you have had a vasectomy. You must not donate sperm while using thalidomide. - Effective birth control must be used for at least 1 month before beginning thalidomide treatment, during thalidomide treatment, and for 1 month after stopping thalidomide. Reliable birth control is necessary even if you have been unable to get pregnant in the past. Two effective forms of birth control must be used at the same time (unless continuous avoidance of sexual intercourse is your method). Consult your doctor. - Immediately report to your doctor if your period is late, or if you have abnormal vaginal (menstrual) bleeding. Thalidomide must not be used during pregnancy. If you become pregnant or think you may be pregnant, inform your doctor immediately. Even a single dose of thalidomide taken by a pregnant woman during her pregnancy can cause severe birth defects. If pregnancy does occur during treatment, this drug must be discontinued immediately. It is not known if this drug is excreted into breast milk. Because of the potential for serious reactions in nursing infants, breast-feeding is not recommended while using thalidomide.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from sunlight and moisture. Brief storage between 59 and 86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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