

Patient Information Leaflet

Thalidomide – THALIDOMIDE®

What is THALIDOMIDE®

Medicine Name	Description
	50 mg gelatin capsule: white
Thalidomide	SOmg SOmg

How should you take your medicine?

Your doctor has determined your medicine dosage.

In your case, the dosage is as follows: mg/day, i.e. 50 mg gelatin capsules every day.

Swallow whole with a glass of water, without opening, chewing, or diluting the capsules.

At a set time, with or without meals. To reduce the drowsiness effect, it is recommended to take the medicine in the evening, one hour before bedtime.

If you forgot to take a dose or in case of vomiting, do not take an additional dose but wait for the time to take the next dose.

Dosage – therapy regimen

Once a day, in the evening, one hour before bedtime									In the evening
With no gaps	D1	D2	D3	D4	D5	D6	D 7	•••	D28

How to get the medicine supply?

This medicine is available in a hospital pharmacy.

A patient's medical record and a signed medical care agreement are required to receive the medication.

Getting this medicine might take time. Be careful and order the medicine in advance. Store this product in its original packaging, away from sources of heat and moisture.

What else do you need to know?

Precautions and monitoring

Laboratory tests are necessary while taking your medication (blood test to monitor blood counts, pregnancy test for women), as well as clinical condition monitoring.

Using contraceptives

This drug may harm an unborn baby. During the entire treatment, you and your partner need to use effective contraception methods (condoms combined with another method).

Interactions with other medications and/or food

The occurrence of interactions between THALIDOMIDE® and your other treatments may have harmful consequences (reduced drug efficacy and tolerance). It is important to tell your pharmacist and doctor about all medications and/or other substances (foods, plants, probiotics, essential oils, nutritional supplements, etc.) that you are taking.

Example: While taking THALIDOMIDE®, it is necessary to avoid using alcohol.

What are possible side effects?

Only the most common side effects are listed below. There might be some other side effects. For additional information, refer to your medicine leaflet or seek advice from your doctor or pharmacist.

SIDE EFFECTS



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Updated on May 9, 2020 Abnormal lab results: low multinuclear neutrophil count (neutropenia), low platelet count (thrombocytopenia), Most common ones low hemoglobin level (anemia) Skin problems: rash, itching, dryness Digestive problems: constipation, nausea Cardiovascular problems: phlebitis, pulmonary artery embolism, shortness of breath, chest pain, bradycardia Neurological problems: sensory disturbances (numbness, tingling, creeps), sensation of burning or electric shock, pain caused by cold, heat, and temperature changes, drowsiness, dizziness Others: infection, fatigue, unusual bleedings, leg and arm swelling WHEN TO ALERT THE MEDICAL TEAM? Digestive problems Tell medical personnel if the > Significant and/or rapid weight loss following conditions are present and in the absence > Very frequent diarrhea, bowel movement over 4 times a day > Severe abdominal pain of specific medical advice > Inability to drink for 24 hours and/or eat for about 48 hours > Bowel movements fewer than 3 times a week Skin problems > Significant blisters or severe peeling of the skin Symptoms suggestive of cardiac toxicity > Shortness of breath, high palpitations, chest pain or tightness > Red, warm to the touch, and painful calf Symptoms suggestive of neurological disorder > Abnormal sensations, such as tingling, creeps > Motor skills and coordination impairment > Memory loss, difficulty concentrating, difficulty speaking > Dizziness Symptoms suggestive of infection > Temperature > 38.5 °C > Cough, throat pain, pain on urination, diarrhea with fever Symptoms suggestive of lysis syndrome > Urine color > Decreased urine output Pain in the side under the ribs **Suspected pregnancy** > Of a woman who received treatment > Of a partner of a man who received treatment HOW TO PREVENT SIDE EFFECTS? Women of childbearing age Pregnancy is contraindicated; the risk of birth defects. During the entire period of treatment and up to 4 weeks after the last dose, use two methods of birth control during sexual intercourse. Do a pregnancy test every month and for 4 weeks after your last dose. Men During the entire period of treatment and up to 1 month after receiving the last dose, use a condom during sexual intercourse. Weight Regularly check your weight in case of digestive problems. Opt for mild soap and moisturizer, pat skin dry. Avoid using any skin irritating products. Skin care For sun protection use broad spectrum sunscreen and avoid sun exposure. Infection Avoid visiting high risk areas (crowds, contact with sick people, ...). A flu and pneumococcal infection vaccine might be recommended for you: it will protect you. Opt for activities contributing to well-being, in particular adjusted and regular physical activities: walking, Fatigue work in the garden, swimming, biking, sports... Alternate periods of activity and rest. Avoid taking anti-inflammatory drugs (ibuprofen, aspirin...) Bleedings Notify your doctor: > if you take blood thinners or thrombocytic antiaggregants: careful monitoring is needed > about surgical or dental intervention. HOW TO ADAPT YOUR DIET?

Constipation

Nausea

Opt for split nutrition consisting of several light meals, liquid and cold dishes.

Opt for a high fiber diet. Drink more water.

Limit consumption of fatty, fried, and spicy foods