

DOMIDE CAPSULE 50MG

Consumer Medication Information Leaflet (RiMUP)

Thalidomide (50mg)

Please make sure you have signed the "Consent for Treatment" and understand the explanation given by your doctor or pharmacist before taking this medicine

Warning

If thalidomide is taken during pregnancy, it can cause severe birth defects or death to an unborn baby. Thalidomide should never be used in women who are pregnant or who could become pregnant while taking the drug. Even a single dose taken by a pregnant woman during her pregnancy can cause severe birth defects.

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What *Domide* is used for

Domide is used in combination with melphalan and prednisolone for the treatment of multiple myeloma patients who are aged 65 years or more, or who cannot be given high dose chemotherapy.

It is used with dexamethasone for patients with newly diagnosed multiple myeloma, to be given before high dose chemotherapy with autologous stem cell rescue.

Domide is used to treat patients who have moderate to severe skin lesions of leprosy (Erythema Nodosum Leprosum), but it is not used as the lone treatment for skin lesions when patients have moderate to severe nerve pain.

Domide is used for preventing and keeping the skin lesions of leprosy from recurring.

How *Domide* works

Domide works by blocking the development of cancer cells, inhibiting blood vessels growing in the cancer, and modulating human immune function.

Before you use *Domide*

- When you must not use it

- You are a woman and are pregnant or want to become pregnant or are likely to become pregnant. If you must take this medicine, please prevent pregnancy.
- You are a man and have unprotected sex with women who may become pregnant. Domide can be found in the semen of patients taking the medication, and this may cause risk to the baby.
- You are allergic to Domide or other components of the drug.

- Before you start use it

Please make sure you have signed the "Consent for Treatment" and understand the explanation given by your doctor or pharmacist before taking this medicine, especially about the effects of Domide on unborn babies and other risk factors (Arterial thromboembolic events- Blood clots in the arteries which lead to heart attack/myocardial infarction; Second primary malignancies- Development of additional types of blood cancer such as acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS).

If you have or have ever had previous viral infection, particularly varicella zona, hepatitis B infection, or HIV, talk to your doctor. Treatment with thalidomide may cause virus to become active again in patients who carry it, resulting in a recurrence of the infection. Your doctor should check whether you have ever had hepatitis B infection.

Tell your doctor if you have high blood pressure from the heart to the lungs.

- Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Domide and other medicines may affect efficacy of each other and result in serious side effects.

Make sure you tell your doctor if you are taking any medicines such as:

- Barbiturates, alcohol, chlorpromazine, and reserpine.
- Medications associated with peripheral neuropathy.
- Oral contraceptives
- Drugs that interfere with hormonal contraceptives, including HIV-protease inhibitors, griseofulvin, modafinil, penicillins, rifampin, rifabutin, phenytoin, carbamazepine, or certain herbal supplements like St. John's Wort.

How to use *Domide*

- How much to use and How long to use it

Multiple Myeloma

-In combination with Melphalan and Prednisolone:

The Domide recommended oral dose is 200 mg per day. A maximum number of 12 treatment cycles with each cycle lasting 6 weeks should be used.

- In combination with Dexamethasone:

The Domide recommended oral dose is 200 mg per day. For induction, 4

treatment cycles with each cycle lasting 4 weeks is recommended.

-Erythema Nodosum Leprosum (ENL)

The Domide recommended starting dose is 100 to 300 mg/day for an episode of cutaneous ENL and is up to 400 mg/day for severe cutaneous ENL. Dosing with Domide should usually continue until signs and symptoms of active reaction have subsided, usually a period of at least 2 weeks.

However your doctor may adjust the dose for you depending on tolerability and disease progression. Your doctor will tell you how much dose and for how long you will need to take it.

Swallow the drug in doses as directed by your doctor or pharmacist.

- When to use it

Take Domide with water before bedtime or an hour after dinner to reduce drowsiness, somnolence and sedation during the day.

- If you forget to use it

If you miss one dose, take it as soon as possible but the timing of the dose should not be close to the next dose. Do not take double doses of Domide at one time.

- If you use too much (overdose)

If you take more Domide than you should, go to the nearest hospital as soon as possible, or contact your doctor immediately. It is suggested to take the medicine pack and this leaflet with you.

While you are using it

- Things you must do

If you miss or you think you have missed a period, inform your doctor as soon as possible.

If you do become pregnant during the treatment with Domide, you must stop

the treatment and inform your doctor immediately.

- Things you must not do

Do not breastfeed when taking Domide as it is not known if thalidomide is passed into human breast milk.

Do not drive a car or operate complex machines if you experience side effects, such as dizziness, tiredness, sleepiness or blurred vision.

Do not drink alcohol while you are taking Domide. Domide may potentiate the drowsiness caused by alcohol.

Do not donate blood while taking Domide.

- Things to be careful of

- 1) These drugs may cause adverse side effects to the baby in the womb.
- 2) Should pregnant women take Domide 50mg capsules, the unborn baby may suffer disability or death, although only one 50mg capsule is taken.
- 3) If you are female, please carry out a pregnancy test and make sure you DO NOT get pregnant while taking the drug Domide 50mg capsules. Pregnancy test should be carried out legally and effectively.
- 4) Do not open or crush Domide capsules. If powder from Domide capsule contacts the skin, wash the skin immediately with soap and water.

Side effects

- 1) Allergic reaction which may present as rash, fever, rapid heartbeat, and low blood pressure.
- 2) Slow heartbeat
- 3) Stevens Johnson Syndrome- the skin becomes red and cracking.
- 4) Seizures
- 5) Feeling sleepy or exhausted
- 6) Shortness of breath, chest pain, or arm or leg swelling.

- 7) Numbness or ill effects as prickle in the limbs, especially your fingers.
- 8) Constipation.
- 9) Increase in blood pressure within blood vessels that supply the lungs which can lead to shortness of breath, tiredness, dizziness, pain in the chest, a faster heartbeat, or swelling in the legs or ankles (pulmonary hypertension).
- 10) Viral infections, including herpes zoster (also known as 'shingles', a viral disease that causes a painful skin rash with blisters) and recurrence of hepatitis B infection (which can cause yellowing of the skin and eyes, dark brown-coloured urine, right-sided stomach pain, fever and feeling nauseous or being sick)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Domide

- Storage

Keep at temperatures less than 30°C. Protect from heat, moisture and direct sunlight. Keep out of reach of children.

- Disposal

Return any unused medication to your pharmacist for safe disposal.

Product Description

- What it looks like
- A hard capsule with a white body and orange cap, imprinted with "THADO" in black print on both of the cap and the body.
- Ingredients
- Active ingredient:
Thalidomide
- Inactive ingredients

Avicel ph-l02; Lactose Monohydrate;
Lactose spray-dried; Corn starch;
Silicon dioxide; Stearic acid;
Magnesium stearate.

- MAL number:

MAL20102065AZ

Manufacturer

TTY Biopharm Company Limited,
Taiwan

Product Registration Holder

Pharm-D Sdn. Bhd. (535448-K)
8B, Jalan 1/137C, Bedford Business Park,
Off Jalan Kelang Lama,
58000 Kuala Lumpur, Malaysia.

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