

Important information for **Thado® (Thalidomide)** patients
Reading the following conditions before taking THADO® (Thalidomide)

- I do understand Thalidomide can cause severe birth defects or death to an unborn baby.
- Thalidomide should never be used in women who are pregnant or who are breastfeeding while taking the drug.
- 【FOR FEMALE PATIENTS】** must use two other effective or highly effective methods of contraception or abstain from heterosexual sexual contact while taking thalidomide.
- 【FOR MALE PATIENTS】** must use condoms during sexual contact while taking the drug.
- Patients should be instructed that they are not permitted to donate blood while taking THADO® (Thalidomide)
- I understand the drug is only for personal use.

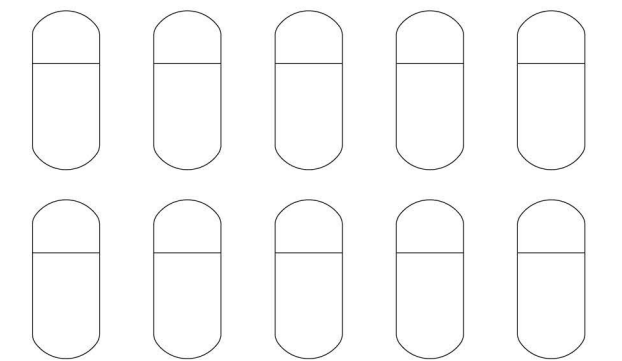
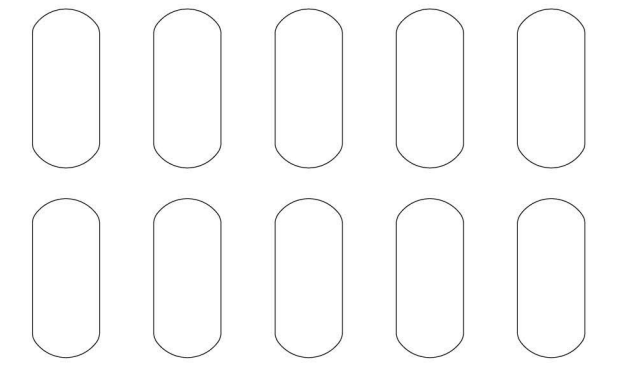
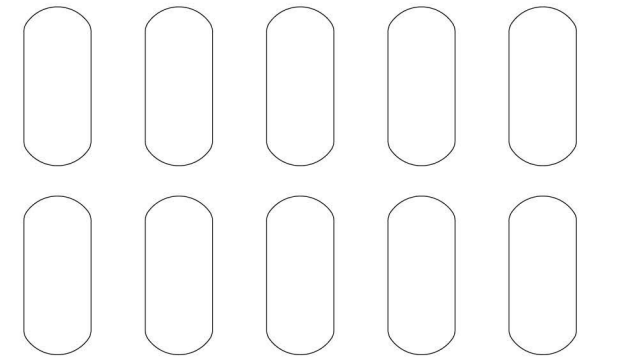
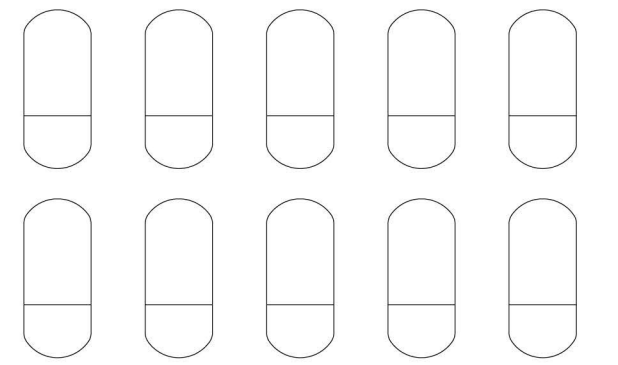
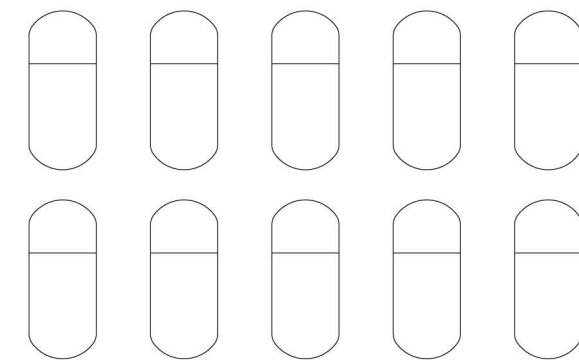
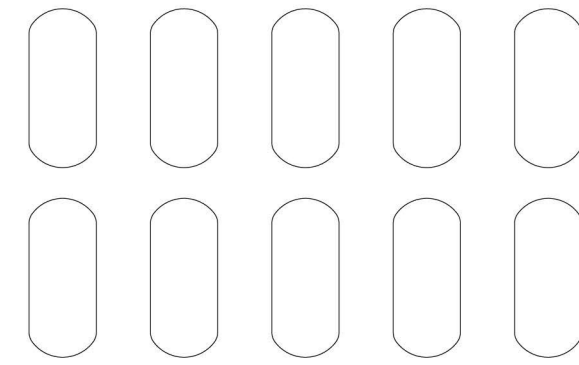
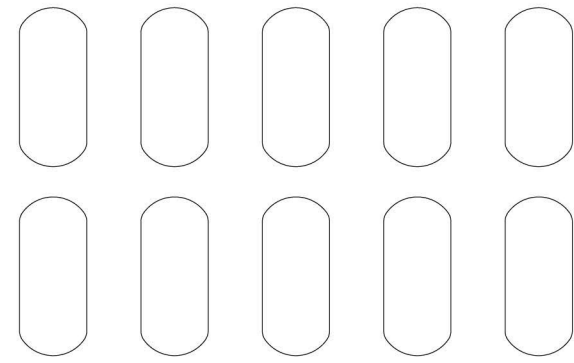
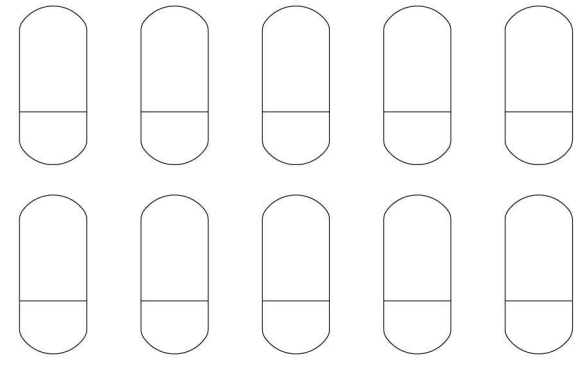
Thalidomide	Oral use only.
Thado® 50mg Capsule	Controlled Medicine
Anti-neoplastic	Caution: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
50 mg	50 mg
60 capsules	60 capsules
Ⓡ	Active Ingredient: Each capsule contains thalidomide 50mg.
<small>IMPORTED AND DISTRIBUTED BY: American Taiwan Biopharm Co., Ltd. 16F Eastwater Building 1 Vipavadeerangsit Soi 5, Vipavadeerangsit Rd., Jomphol, Jatuiak Bangkok 10900</small>	Indication: Details please see package insert.
<small>Manufactured by: TTY Biopharm Company Limited 838, Chung-Hwa Rd., Sec. 1, Chung-Li Dist., Taoyuan City, 32069, Taiwan</small>	Side effect and precautions: See package insert.

Thado	Lot No./Exp. Date: Mfg. Date: (กรุณาส่ง)
Dosage and Administration: Directions for use see package insert.	ยาควบคุมพิเศษ
Storage Conditions: Store at temperatures not exceeding 30°C. Avoid heat, moisture and direct light exposure. Please keep out of the reach of children	ใช้เฉพาะสถานพยาบาล
<small>FDA Reg. No.</small>	

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TDOCACPHL



security label



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Thalidomide

Thado® 50mg Capsule

Anti-neoplastic



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Oral use only.

Controlled Medicine

Caution:
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50 mg
60 capsules

Active Ingredient:
 Each capsule contains
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Indication:
 Details please see
 package insert.

**Side effect and
 precautions:**
 See package insert.

Dosage and Administration:

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Thado

Lot No./Exp. Date: Mfg. Date:
 (ยาสินขาย)

ยาควบคุมพิเศษ

ใช้เฉพาะสถานพยาบาล

Thalidomide

Thado® 50mg Capsule

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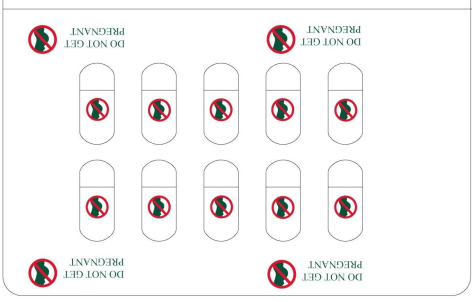
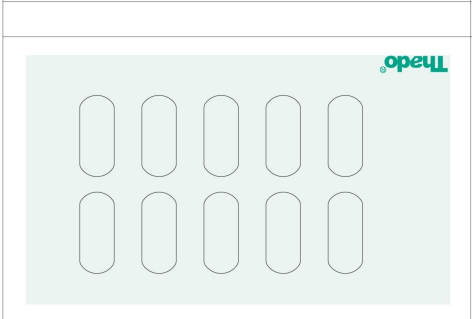
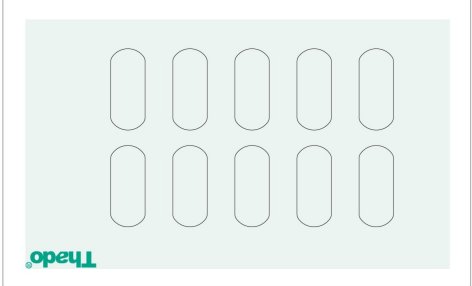
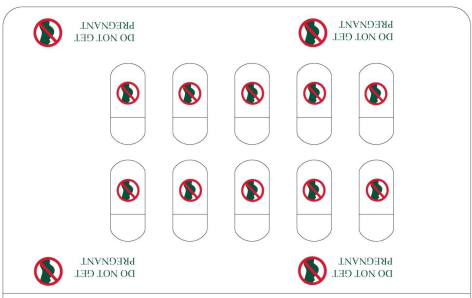
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ยาควบคุมพิเศษ

ใช้เฉพาะสถานพยาบาล

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WARNING
Warning, severe, life-threatening human birth defects.
Thalidomide is taken during pregnancy, it can cause severe birth defects or death to an unborn baby. Thalidomide should never be used by 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.
Please see the following boxed warnings containing special information for prescribers, female patients, and male patients.

Before starting treatment, women of childbearing potential should have a pregnancy test (sensitivity of at least 50 mIU/mL). The test should be performed within the 24 hours prior to beginning thalidomide therapy. A prescription for thalidomide for a woman of childbearing potential must not be issued by the prescriber until a written report of a negative pregnancy test has been obtained by the prescriber. Once treatment has started, pregnancy testing should occur weekly during the first 4 weeks of use, then pregnancy testing should be repeated at 4 weeks in women with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks. Pregnancy testing and counseling should be performed if a patient misses her period or if there is any abnormality in menstrual bleeding.
If pregnancy does occur during thalidomide treatment, thalidomide must be discontinued immediately.

FOR FEMALE PATIENTS
(Thalidomide) is contraindicated in WOMEN of childbearing potential unless alternative therapies are considered inappropriate AND the patient MEETS ALL OF THE FOLLOWING CONDITIONS (i.e., she is essentially unable to become pregnant while on thalidomide therapy):

- she understands and can reliably carry out instructions
- she is capable of complying with the mandatory contraceptive measures, pregnancy testing
- she has received both oral and written warnings of the hazards of taking thalidomide during pregnancy and of exposing a fetus to the drug.
- she has received both oral and written warnings of the risk of possible contraception failure and of the need to use two reliable forms of contraception simultaneously, unless continuous abstinence from heterosexual sexual contact is the chosen method. Sexually mature women who have not undergone a hysterectomy or who have not been postmenopausal for at least 24 consecutive months are considered to be women of childbearing potential.
- she acknowledges, in writing, her understanding of these warnings and of the need for using two reliable methods of contraception for 4 weeks prior to beginning thalidomide therapy, during thalidomide therapy, and for 4 weeks after discontinuation of thalidomide therapy.
- she has had a negative pregnancy test with a sensitivity of at least 50 mIU/mL, within the 24 hours prior to beginning therapy.
- if the patient is between 12 and 18 years of age, her parent or legal guardian must have read this material and agreed to ensure compliance with the above.

FOR MALE PATIENTS
(Thalidomide) is contraindicated in sexually mature MALES unless the PATIENT MEETS ALL OF THE FOLLOWING CONDITIONS:

- he understands and can reliably carry out instructions.
- he is capable of complying with the mandatory contraceptive measures that are appropriate for men.
- he has received both oral and written warnings of the hazards of taking thalidomide and exposing a fetus to the drug.
- he has received both oral and written warnings of the risk of possible contraception failure and of the presence of thalidomide in semen. He has been instructed that he must always use a latex condom during any sexual contact with women of childbearing potential, even if he has undergone a successful vasectomy.
- he acknowledges, in writing, his understanding of these warnings and of the need to use a latex condom during any sexual contact with women of childbearing potential, even if he has undergone a successful vasectomy. Sexually mature women who have not undergone a hysterectomy or who have not been postmenopausal for at least 24 consecutive months are considered to be women of childbearing potential.
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Side effect
(Thalidomide) is associated with drowsiness/somnolence, peripheral neuropathy, dizziness/orthostatic hypotension, neutropenia, Hypersensitivity, bradycardia, and HIV viral load increase.

Thalidomide
Thado® 50mg Capsule
Anti-neoplastic

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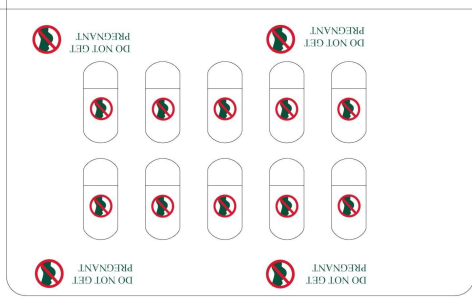
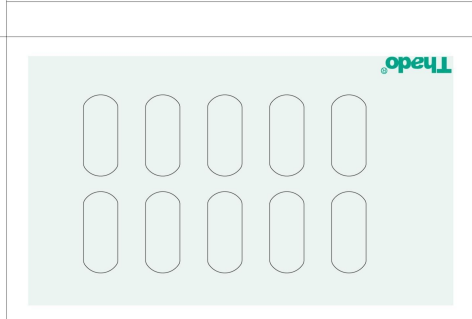
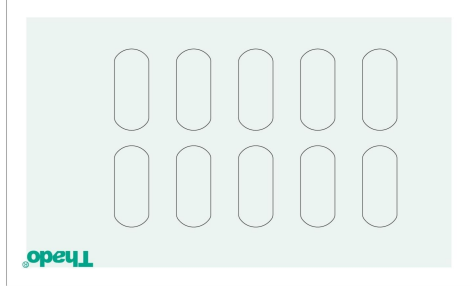
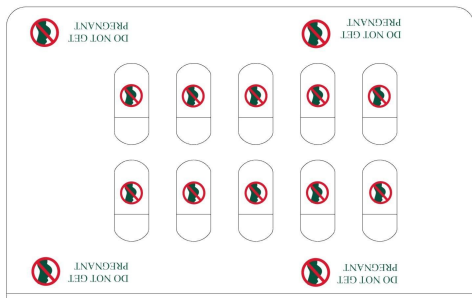
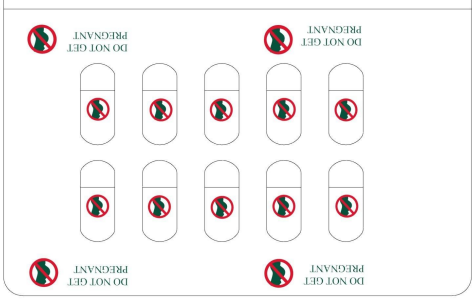
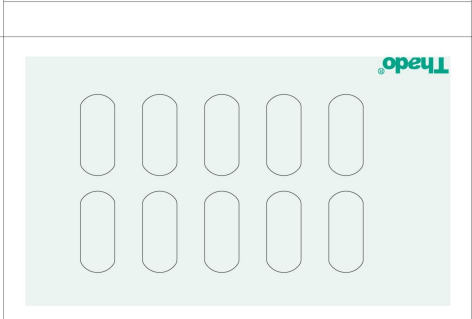
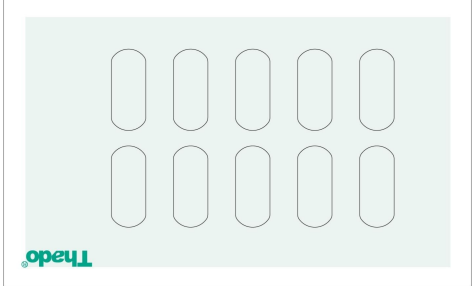
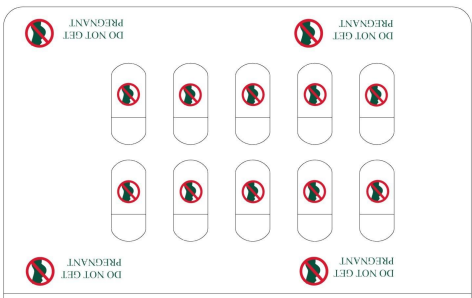
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- she understands and can reliably carry out instructions
- she is capable of complying with the mandatory contraceptive measures, pregnancy testing, and if she has received both oral and written warnings of the hazards of taking thalidomide during pregnancy and of exposing a fetus to the drug.
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Anti-neoplastic



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Mfg. Date:

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