

**PATIENT GUIDE  
TO DOMIDE RMP  
PROGRAM**

## **Patient Guide to DOMIDE RMP Program**

This guide provides you important information about:

### The risks of **Domide** (thalidomide)

- Birth defects (deformed babies) or death of an unborn baby
- Blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism)

### The **Domide** RMP program

- What females who can get pregnant need to know
- What males need to know

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## **Risks of DOMIDE (thalidomide)**

**Domide** can cause harm to an unborn baby when given to a pregnant female. **Domide** causes a high frequency of severe and life-threatening birth defects (deformed babies) or death of an unborn baby, even after a single dose (1 capsule [regardless of strength]).

**Domide** must not be used by pregnant females or by females who are able to get pregnant who are not using acceptable birth control or avoiding sex with a male. Females who are able to get pregnant must avoid pregnancy while taking **Domide**.

**Domide** causes a higher chance for blood clots in your veins (deep vein thrombosis) and lungs (pulmonary embolism).

**This is not a comprehensive description of risks associated with the use of Domide. Please ask your doctor for additional information regarding risks associated with its use.**

## **What is the DOMIDE RMP program?**

To avoid serious risks to unborn babies, **Domide** is only available under a restricted distribution program called the “**Domide** RMP Program”. Only certified prescribers can prescribe **Domide**. In order to receive **Domide**, patients must be enrolled in the **Domide** RMP program and agree to follow the requirements.

For more information about **Domide** and the **Domide** RMP program, please ask your doctor.

## How to receive your first prescription for DOMIDE (thalidomide)

### For Females:

#### Counseling

Your doctor will counsel you on why and how you and your partner should prevent pregnancy. Your doctor will also inform you not to share the drug, not to donate blood, and about using two effective birth control methods (at least one highly effective method and one effective method) at the same time. You should be instructed not to extensively handle or open **Domide** capsules.

#### Pregnancy Test

If you can get pregnant, you must take a pregnancy test during consultation, or in the 3 days prior to the visit to your doctor before getting a **Domide** prescription.

#### Enrollment

You will then complete the **Patient Letter of Consent**. You should tick **ALL** the boxes next to each statement under 'For All Patients' AND 'Females of Reproductive Potential Only' (if you can get pregnant) sections in order to be eligible to receive **Domide**.

### For Males:

#### Counseling

Your doctor will counsel you on why and how you and your partner should prevent pregnancy. Your doctor will also inform you not to share the drug, not to donate blood or sperm, and about appropriate contraceptive use. You should be instructed not to extensively handle or open **Domide** (thalidomide) capsule.

#### Enrollment

You will then complete the **Patient Letter of Consent**. You should tick **ALL** the boxes next to each statement under 'For All Patients' AND 'Males Only' sections in order to be eligible to receive **Domide**.

## How to receive your subsequent prescriptions for DOMIDE (Thalidomide)

### For Females:

#### Counseling

Your doctor will counsel you on why and how you and your partner should prevent pregnancy. Your doctor will also inform you not to share the drug, not to donate blood, and about using two effective birth control methods (at least one highly effective method and one effective method) at the same time. You should be instructed not to extensively handle or open **Domide** capsules.

#### Pregnancy Test

If you can get pregnant, you need to repeat pregnancy test every 4 weeks, including 4 weeks after the end of treatment. You need to take pregnancy test on the day of your doctor visit or in the 3 days prior to the visit to your doctor.

### For Males:

#### Counseling

Your doctor will counsel you on why and how you and your partner should prevent pregnancy. Your doctor will also inform you not to share the drug, not to donate blood or sperm, and about appropriate contraceptive use. You should be instructed not to extensively handle or open **Domide** (thalidomide) capsule.

## What do all patients need to know about the DOMIDE RMP program?

### General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. Just **one capsule** taken by a pregnant female can cause severe birth defects.
- **Domide** (thalidomide) does not induce abortion of the fetus and should never be used for contraception.
- **Domide** must be kept out of the reach of children.
- Do not open or unnecessarily handle **Domide** capsules. If a broken capsule (or the powder in the capsule) comes in contact with your skin, wash the area with soap and water.
- Keep **Domide** in a cool, dry place.
- Do **not** donate blood while you are taking **Domide**, during breaks (dose interruptions),

and for 4 weeks after stopping **Domide**.

- Unused **Domide** capsules should be returned for disposal to your **Domide** prescriber, or to the pharmacy that dispensed the **Domide** to you.

### Warning

**Domide** can cause other health problems called “side effects.” Ask your doctor about other side effects associated with **Domide**.

Blood clots have been reported in patients taking thalidomide, especially when used with other cancer drugs. Your healthcare provider may recommend treatment that could help prevent blood clots. Talk to your healthcare provider if you have shortness of breath, chest pains, or arm or leg swelling

**Be sure to report all side effects to your doctor immediately.**

## What do females who can get pregnant need to know about the DOMIDE RMP program?

### A. Before taking Domide (thalidomide)

- You must sign the **Domide** (thalidomide) Letter of Consent that says you understand that **Domide** should not be used during pregnancy, and that you agree not to become pregnant while taking **Domide**.
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least highly one effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking **Domide**. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons.

Highly effective birth control methods	Additional effective birth control methods	Unacceptable forms of contraception
Birth control pill Contraceptive Injection (done 4 times a year) Intrauterine Device (IUD) Female sterilisation	Male latex or synthetic condom Spermicide Diaphragm (to be used with spermicide) Cervical cap (to be used with	<ul style="list-style-type: none"> <li>● Natural family planning (rhythm method) or breastfeeding</li> <li>● Fertility awareness</li> <li>● Withdrawal</li> </ul>

(permanent)	spermicide)  Female condom  Vaginal ring	● Cervical shield*  *(A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception).
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- Your doctor must give you a pregnancy test during consultation, when Domide is prescribed or in the 3 days prior to the visit to the your doctor before you receive your first prescription for **Domide**. If you are pregnant, you cannot take **Domide**.
- You will have pregnancy tests before start taking **Domide** and while taking **Domide**, even if you agree not to have sex with a male.
- Your doctor will talk with you about your birth control options. Tell your doctor what medicines or dietary supplement you take to make sure that they do not interfere with your birth control methods
- **Remember, not having sex is the only method of birth control that is 100% effective.**

#### **B. While taking Domide**

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.
- **Remember, not having sex is the only method of birth control that is 100% effective.**
- You must talk to your doctor before changing any birth control methods you have already agreed to use.
- You will have a pregnancy test performed by your doctor:
  - Every 4 weeks during treatment, including 4 weeks after the end of treatment
  - If you miss your period or have unusual menstrual bleeding, or
  - If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control or if you think your birth control has failed, stop taking **Domide** (thalidomide)



immediately and call your doctor right away. Your doctor will discuss your options, which may include emergency birth control. Do not wait until your next appointment to tell your doctor if you miss your menstrual period or if you think you may be pregnant.

- If you get pregnant, or think you may be pregnant, you must immediately stop taking **Domide**. Contact your doctor immediately to discuss your pregnancy. If you do not have an obstetrician, your doctor will refer you to one for care and counseling.
- You must not breastfeed a baby while you are taking Domide.

### **C. After you have stopped taking Domide (thalidomide)**

- You must continue to use at the same time at least 1 effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
  - For at least 4 weeks after stopping **Domide**, or
  - Do not have any sex with a male for 4 weeks after stopping **Domide**
  - See also “General guidelines” on page 5 for requirements for all patients

## **What do males need to know about the DOMIDE RMP program?**

You must use a latex or synthetic condom, **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm) .

### **A. Before taking Domide**

- You must sign **Domide** Patient Letter of Consent. You must agree that while taking Domide you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

### **B. While taking Domide**

- You must use a latex or synthetic condom **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- **Remember, not having sex is the only method of birth control that is 100% effective**
- You must tell your doctor right away if you had sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner may be pregnant or

if your partner is pregnant.

- You must **not** donate sperm while taking Domide (including during breaks [dose interruptions])

### **C. After you have stopped taking Domide**

- For 4 weeks after receiving your last dose of Domide, you must use a latex or synthetic condom, **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping Domide
- See also “General guidelines” on page 5 for requirements for all patients.

## **Warning to patients taking DOMIDE (thalidomide)**

### **Attention to females:**

Do **not** take Domide if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

### **Attention to males:**

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking Domide, during breaks (dose interruptions), and for 4 weeks after stopping Domide .

### **Attention all patients:**

You must **not** donate blood while taking Domide , during breaks (dose interruptions), and for 4 weeks after stopping Domide.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. Just **one capsule** taken by a pregnant female can cause severe birth defects.

Domide must be kept out of the reach of children. Return any unused Domide capsules for disposal to your Domide prescriber, or to the pharmacy that dispensed the Domide to you.