PATIENT GUIDE TO DOMIDE RISK MANAGEMENT PROGRAM (RMP)

This guide provides you with important information about the risks associated with DOMIDE (thalidomide) and the requirements of the DOMIDE Risk Management Program (RMP) to ensure safe use of DOMIDE. Please make sure that you have read and understood the information in the guide prior to starting treatment with DOMIDE. You must adhere to the program requirements to receive DOMIDE treatment. If you have questions or concerns about your treatment, please consult your doctor.

Risks Associated with DOMIDE

1. DOMIDE can cause **severe and life-threatening birth defects (deformed babies)** or **death of an unborn baby**. If you are pregnant or planning to become pregnant, you **MUST NOT TAKE DOMIDE.**
2. DOMIDE can **increase the risk of blood clots** in your veins (deep vein thrombosis) and lungs (pulmonary embolism). Before starting DOMIDE, inform your doctor about all the medications and supplements you are taking, as some can increase the risk of blood clots.
   Seek immediate medical help if you experience any of the following symptoms:
   - Shortness of breath, chest pain, or swelling of your arms or legs
   - Chest pain spreading to jaw, neck, arms, back, or stomach, sweating, shortness of breath, nausea, or vomiting
   - Sudden numbness or weakness (especially on one side of the body), severe headache, confusion, or problems with vision, speech, or balance

Disclaimer: This is not a comprehensive description of risks associated with the use of DOMIDE. Please consult your doctor for additional information regarding risks associated with DOMIDE use.

About the DOMIDE RMP

- To prevent serious risks to unborn babies, DOMIDE is only available through a restricted distribution program known as the DOMIDE Risk Management Program (RMP). To be eligible for DOMIDE treatment, you must agree to adhere to the requirements of the DOMIDE RMP.
- Your doctor will explain **BOTH** this guide and the Patient Letter of Consent for DOMIDE RMP to you.
- You should **complete and sign** the Patient Letter of Consent after reading this guide and agreeing to the terms outlined in the Patient Letter of Consent.

General Guidelines for All Patients

1. Do not share DOMIDE with anyone even if they have symptoms like yours. Just one capsule of DOMIDE taken by a pregnant female can cause severe birth defects.
2. DOMIDE does not induce abortion of the fetus and should never be used for contraception.
3. Do not donate blood while taking DOMIDE, during treatment breaks, and for 4 weeks after discontinuation.
4. Store DOMIDE below 30°C. Keep out of the reach of children.
5. Avoid opening, crushing, or handling DOMIDE capsules unnecessarily.
   - Wash the exposed area with soap and water immediately upon contact with DOMIDE content.
6. Unused DOMIDE capsules should be returned for disposal to your DOMIDE prescriber or to the dispensing pharmacy.

For Females of Reproductive Potential Taking DOMIDE

You should:

- **AVOID getting pregnant and REFRAIN from breastfeeding:**
  - For at least 4 weeks before starting DOMIDE
  - While taking DOMIDE
  - During any treatment breaks (interruptions) with DOMIDE
  - For at least 4 weeks after stopping DOMIDE
- Perform a **medically supervised pregnancy test:**
  - During consultation or 3 days prior to your visit before DOMIDE treatment initiation
  - Every 4 weeks during treatment, or at an interval advised by your doctor
  - 4 weeks after the last DOMIDE dose
  - If you miss your period or experience unusual bleeding
  - If you did not receive your medication within 7 days from your last pregnancy test
- **STOP taking DOMIDE and inform your doctor IMMEDIATELY** if you:
  - Become pregnant while taking DOMIDE
  - Suspect that you missed your period due to pregnancy or have unusual menstrual bleeding
  - Stop using birth control
  - Have unprotected sex or suspect birth control failure
  - Think for any reason that you are pregnant or might be pregnant
- Use **at least 1 highly effective method** and **at least 1 additional effective method** of birth control simultaneously for every sexual activity with a male unless otherwise recommended by your doctor:
  - Starting at least 4 weeks before taking DOMIDE
  - While taking DOMIDE
  - During breaks (dose interruptions)
  - For at least 4 weeks after stopping DOMIDE

Highly effective birth control methods	**Additional effective birth control methods**
1. Birth control pill 2. Contraceptive injection (done 4 times a year) 3. Intrauterine Device (IUD) 4. Female sterilization (permanent)	1. Male latex or synthetic condom 2. Spermicide ± diaphragm or cervical cap *Both diaphragm and cervical cap **CANNOT BE USED AS STANDALONE** contraceptive methods* 3. Female condom 4. Vaginal ring

The following contraceptive methods are considered **unacceptable:**

1. Natural family planning (rhythm method)
2. Fertility awareness techniques
3. Withdrawal method
4. Cervical shield (not be confused with a cervical cap)

ABSTAINING FROM SEXUAL ACTIVITIES IS THE ONLY 100% EFFECTIVE BIRTH CONTROL METHOD.

- Discuss acceptable birth control options with your doctor to prevent pregnancy before, during, and after treatment with DOMIDE.
- Inform your doctor about other medications and supplements you are taking to ensure that they do not interfere with your birth control methods.
- Inform your doctor before changing any birth control methods you have already agreed to use.

For Males Taking DOMIDE

- DOMIDE can be present in human semen.
- Males, including those who have had a vasectomy (tying of the tubes to prevent the passing of sperm), must always use a latex or synthetic condom during any sexual contact with a pregnant woman or woman of reproductive potential while taking DOMIDE, during treatment breaks, and for up to 4 weeks after stopping DOMIDE.
- Avoid unprotected sexual contact with a pregnant woman or woman of reproductive potential.
- Do not donate sperm while taking DOMIDE, during treatment breaks, and for 4 weeks after stopping DOMIDE.

Inform your doctor IMMEDIATELY if you engaged in unprotected sexual contact with a pregnant woman or woman of reproductive potential OR suspect that your partner is or may be pregnant.

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