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HEALTHCARE PROFESSIONAL GUIDE TO

DOMIDE RISK MANAGEMENT PROGRAM (RMP)

This guide provides key information about DOMIDE (Thalidomide) and its Risk Management Program (RMP).

Due to its teratogenic risk, DOMIDE is available only through a restricted distribution system known as the DOMIDE RMP in Singapore. Only healthcare professionals (i.e., prescribers, pharmacists and nurses) registered under the DOMIDE RMP are eligible to prescribe/dispense DOMIDE. To receive DOMIDE, patients must enroll in the DOMIDE RMP and agree to adhere to its requirements. For more information, contact regulatory@pharmd.com.sg or +65 6837 2122.

ABOUT DOMIDE

Indication

- DOMIDE in combination with melphalan and prednisone is indicated for the treatment of patients with untreated multiple myeloma ≥65 years or ineligible for high-dose chemotherapy.
- DOMIDE in combination with dexamethasone is indicated for induction therapy prior to high-dose chemotherapy with autologous stem cell rescue, for the treatment of patients with untreated multiple myeloma.

Risk of embryo-fetal toxicity

- A known teratogen, DOMIDE can cause severe birth defects or embryo-fetal death if taken during pregnancy.
- DOMIDE should **never be used by females who are pregnant or who could be pregnant** while taking the drug. Even a single dose taken by a pregnant woman during her pregnancy can cause severe birth defects.
- Females of reproductive potential may be treated with DOMIDE if they take adequate precautions to avoid pregnancy.

Risk of venous thromboembolism

- The use of DOMIDE in combination with standard chemotherapeutic agents including dexamethasone in multiple myeloma results in an increased risk of venous thromboembolism, such as deep vein thrombosis and pulmonary embolism.
- Consider thromboprophylaxis based on assessment of patient's underlying factors.
- Instruct patients to seek medical attention if they experience symptoms such as shortness of breath, chest pain or swelling in the arms or legs.

Refer to the Singapore package insert for DOMIDE for full prescribing information.

DOMIDE RMP REQUIREMENTS

Healthcare Professional Registration

Only registered prescribers under the DOMIDE RMP can prescribe DOMIDE and only registered pharmacists/nurses can dispense DOMIDE.

To register in the program, each healthcare professional must complete the following steps only ONCE:

1. Complete and sign the Healthcare Professional Letter of Undertaking (HCP LOU).
2. Submit the HCP LOU via email (regulatory@pharmd.com.sg) to register in the DOMIDE RMP.
3. Obtain confirmation of registration into the DOMIDE RMP from Pharm-D Singapore before initiating patients on DOMIDE treatment.

This document has been approved by HSA as of 15-08-2024

Patient Enrollment

Patients enrolled into the DOMIDE RMP should be capable of complying with the requirements for safe use of DOMIDE.

To enroll in the program, each patient must complete the following steps only ONCE:

1. The registered prescriber and the patient must complete the Patient Letter of Consent (LOC) before the initiation of DOMIDE therapy.
2. The signed Patient LOC should be kept in the hospital or clinic. *Ensure ALL boxes in the Patient LOC are ticked.*

INFORMATION FOR HEALTHCARE PROFESSIONALS

FOR ALL PATIENTS

All patients must be provided with the Patient Guide to DOMIDE RMP explaining the safe use of DOMIDE.

General counselling points

- Provide comprehensive counselling on the risk and benefits of DOMIDE therapy, including birth defects, venous thromboembolism and other side effects, and important precautions to be taken for DOMIDE.
- Counsel patients not to share DOMIDE capsules, not to donate blood during treatment (including dose interruptions) and for 4 weeks after the last dose.
- Instruct patients not to extensively handle or open DOMIDE capsules and to store them in blister packs until ingestion.
- Instruct patients to return unused DOMIDE capsules for disposal to their prescriber or the dispensing pharmacy.

FOR FEMALE PATIENTS

Determine if the female patient is of reproductive potential

Females of Reproductive Potential	Females Not of Reproductive Potential
All females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the Females Not of Reproductive Potential category	• Age ≥ 50 years and naturally amenorrheic for ≥ 1 year (Amenorrhea following cancer therapy or during breast-feeding does not rule out childbearing potential) • Premature ovarian failure confirmed by a specialist gynaecologist • Previous bilateral salpingo-oophorectomy, or hysterectomy. • XY genotype, Turner's syndrome, uterine agenesis

Females of Reproductive Potential

1. **Pregnancy test requirements**

   Before initiating treatment:
   - Obtain a negative pregnancy test during consultation, at the time of DOMIDE prescription, or within 3 days prior to the visit once the patient has been using effective contraception for at least 4 weeks.

   Follow-up and end of treatment:
   - Perform medically supervised pregnancy tests every 4 weeks during treatment, including 4 weeks after treatment cessation, except in cases of confirmed tubal sterilization. These tests should coincide with the prescribing visit or within 3 days prior to it.
   - **Discontinue DOMIDE immediately** if a patient misses her period or experiences abnormal menstrual bleeding. Conduct a pregnancy test and provide counseling.
   - Patients must refrain from breastfeeding while undergoing DOMIDE treatment.

   In the event of pregnancy during treatment:
   - **Discontinue DOMIDE immediately** upon pregnancy confirmation.
   - Promptly report any pregnancies in female patients or female partners of male patients prescribed DOMIDE and pregnancies with congenital malformation associated with DOMIDE via email to regulatory@pharmd.com.sg.
   - Refer the pregnant patient to an obstetrician/gynecologist with expertise in reproductive toxicity for further evaluation and counseling.

2. **Contraception requirements**

Female patients of reproductive potential must practice either:

A. **COMPLETE ABSTINENCE** from heterosexual sexual contact/ intercourse; or
B. **EMPLOY TWO EFFECTIVE CONTRACEPTIVE METHODS** simultaneously (comprising at least one highly effective and one additional effective method)

Reiterate to all patients that **ABSTAINING FROM SEXUAL INTERCOURSE IS THE ONLY 100% EFFECTIVE BIRTH CONTROL METHOD.**

- Counsel on the use of appropriate contraception, including emergency contraception, with every new prescription before and during DOMIDE treatment.
- The two effective contraceptive methods should be initiated at least 4 weeks before commencing DOMIDE therapy, continued during therapy (including dose interruptions), and maintained for at least 4 weeks following treatment discontinuation.
- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the efficacy of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, two alternative contraceptive methods may be employed simultaneously during periods of concomitant use and for 4 weeks following treatment cessation.

*The two effective contraceptive methods entail using **at least one highly effective method and at least one additional method** of birth control simultaneously for every sexual intercourse with a male.*

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)

3. **Prescription/dispensing requirements**
   - Prescribe or dispense a maximum of a 4-week (28-day) supply with no automatic refills.

Females Not of Reproductive Potential

- Female patients not of reproductive potential must confirm that she is not currently pregnant and does not possess reproductive potential, either due to having experienced natural menopause for at least 12 months or having undergone a hysterectomy and/or bilateral oophorectomy.
- A parent or guardian must confirm that a prepubertal female child is not pregnant and does not have reproductive potential, either because menstruation has not yet commenced and/or the child will abstain from heterosexual sexual contact for at least 4 weeks before, during, and after DOMIDE therapy, including during dose interruptions.

FOR MALE PATIENTS

- Male patients must be instructed to use a latex or synthetic condom for every instance of sexual intercourse with a female of reproductive potential during treatment and for 4 weeks following the last DOMIDE dose, regardless of having undergone a successful vasectomy.
- The risk to the developing fetus from the semen of male patients using DOMIDE is **unknown**.
- Male patients must be instructed **NOT** to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last DOMIDE dose.

Disclaimer: This is not a comprehensive description of risks associated with the use of DOMIDE. Please refer to the Singapore package insert, which includes Boxed WARNINGS, CONTRAINDICATIONS, WARNING AND PRECAUTIONS, AND ADVERSE REACTIONS, for detailed information on DOMIDE usage.

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