Revlimid® (lenalidomide) capsules

IMPORTANT INFORMATION

for people who are taking REVLIMID® (lenalidomide)

Introducing the *i-access*® program

REVLIMID (lenalidomide) is structurally related to thalidomide. Thalidomide is a known teratogen that causes severe life-threatening human birth defects. If REVLIMID is taken during pregnancy, it may cause birth defects or death to an unborn baby.

To avoid foetal exposure, REVLIMID is available only under a special distribution program called the *i-access* program.

The *i-access* program is designed to ensure that REVLIMID is always prescribed and taken in the recommended way.

Key features of the program

- Only prescribers registered with the *i-access* program can prescribe REVLIMID
- Only pharmacies registered with the *i-access* program can dispense REVLIMID
- Only patients who have been formally enrolled in the *i-access* program can receive REVLIMID
  - Eligible individuals must sign an *i-access* Patient Consent Form and agree to fully comply with all requirements of the *i-access* program

Remember: REVLIMID may cause birth defects or death to unborn babies

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Special *i-access* program requirements for women who are able to become pregnant*

Important: Do NOT become pregnant:

- During the 4 weeks before starting REVLIMID treatment
- While taking REVLIMID
- During any interruption in REVLIMID treatment
- During the 4–week period following the conclusion of your REVLIMID treatment

Before starting treatment:

- **You must sign an *i-access* Patient Consent Form, agreeing not to become pregnant while taking REVLIMID**
- **You must use at least one highly effective and preferably one additional effective form of birth control (contraception) during the 4-week period before starting REVLIMID†**
- **You must have one negative medically supervised pregnancy test confirmed by your doctor**
  - Either at the time of consultation, or in the 3 days prior to the visit to the doctor
  - The pregnancy test must be medically supervised and not a pregnancy test from a chemist

*Includes: women who are menstruating, amenorrhoeic due to previous medical treatment, < 50 years of age and/or peri–menopausal; women who have not been in natural menopause for ≥ 12 consecutive months

†Highly effective forms of birth control include intra–uterine device (IUD) (copper IUDs are not recommended), hormonal methods‡ (birth–control pills, patch, injections, implants, ring), tubal sterilisation or partner's vasectomy (confirmed by 2 negative semen analyses). Additional effective forms of birth control include diaphragm, cervical cap or latex/polyurethane condom by her male partner.

‡For REVLIMID, progesterone only pills are recommended. Combined oral contraceptives are not recommended.

During treatment:

- **You must continue to use at least one highly effective and preferably one additional effective form of birth control (contraception)**
- **You must also undergo regular medically supervised pregnancy tests, regardless of whether continuous abstinence is practised**
  - Every 4 weeks during treatment

  And
  - The pregnancy tests should be performed on the day of the visit to the doctor or in the 3 days prior to the visit
- **You must not breastfeed or donate blood**
- **Never share your REVLIMID capsules**

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant or have sexual intercourse without using an effective means of birth control (contraception):

- Tell your doctor immediately and have a pregnancy test

For 4 weeks after treatment:

- **You must continue to use at least one highly effective and preferably one additional effective form of birth control (contraception)**
- **You must continue the medically supervised pregnancy tests every 4 weeks, ensuring that a pregnancy test is conducted 4 weeks after stopping treatment**
- **You must not breastfeed or donate blood**

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant or have sexual intercourse without using an effective means of birth control (contraception):

- Tell your doctor immediately and have a pregnancy test

i-access program requirements for women who are NOT able to become pregnant

Before starting treatment:

- **You must sign an *i-access* Patient Consent Form, indicating that you are not pregnant and do not have the ability to have children**
  - This means that you are over 50 and have been naturally postmenopausal for at least 12 months, have had your uterus removed (hysterectomy) or have had both ovaries removed

During treatment:

- **You must not donate blood**
- **Never share your REVLIMID capsules**

For 4 weeks after treatment:

- **You must not donate blood**

i-access program requirements for men

Before starting treatment:

- REVLIMID is present in semen. You must therefore sign an *i-access* Patient Consent Form, agreeing to use a latex* condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy)

During treatment:

- You must use a latex condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy)
- You must tell your doctor immediately if you have sexual intercourse with a woman without using a latex condom, or if you think for any reason that your partner may be pregnant
- You must not donate blood or sperm
- Never share your REVLIMID capsules

For 4 weeks after treatment:

- You must continue to use a latex condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy)
- You must tell your doctor if you have sexual intercourse with a woman without using a latex condom, or if you think for any reason that your partner may be pregnant
- You must not donate blood or sperm

*If allergic to latex, any female sexual partner must use at least one highly effective and preferably one additional effective method of contraception. Please discuss with your doctor.

Want to know more?

For more information about REVLIMID and/or the *i-access* program:

- Speak with your doctor
- Call **Celgene Australia on 0800 526 529 (select option 1)**

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