Patient consent form

THALOMID® (thalidomide) and REVLIMID® (lenalidomide) are available only under a special distribution program. This program is called *i-access*®.

Patient details

Patient's name (please print)

Address

Suburb | City | Country | Postcode

Phone | Mobile | Date of birth | Sex ☐ Male ☐ Female

Prescriber section

I have fully explained to the patient the nature, purpose and risks of treatment with THALOMID (thalidomide) or REVLIMID (lenalidomide), especially the potential risks to women of childbearing potential. I have asked the patient if he/she has any questions regarding treatment with THALOMID (thalidomide) or REVLIMID (lenalidomide) and have answered those questions to the best of my ability. I will comply with all of my obligations and responsibilities as a prescriber registered with the *i-access* program.

Diagnosis

Starting treatment: ☐ THALOMID ☐ REVLIMID

Has the patient received the following therapies? (please select all that apply)

☐ Thalidomide ☐ SCT ☐ Bortezomib ☐ None

Is the patient a woman of childbearing potential?* ☐ Yes ☐ No

Prescriber's name (please print)

Institution

Address

Suburb | City

Country | Postcode

Phone | Fax

Prescriber's signature | Date

*Please refer over page for criteria relating to women of non-childbearing potential.

Information on the requirements of the *i-access* program has been provided to me. I understand that if I do not follow all my doctor's instructions and comply with all the requirements of the *i-access* program, I will not be able to receive THALOMID (thalidomide) or REVLIMID (lenalidomide).

I understand that my personal and medical data will be collected by Celgene for the purposes of the *i-access* program. I permit my healthcare providers and pharmacies to disclose to Celgene (and its contractors) my personal and medical information for the following purposes: **(a)** to minimise the risks associated with the use of THALOMID and REVLIMID; **(b)** to maximise the safety, convenience and access to THALOMID and REVLIMID; **(c)** to coordinate the delivery of THALOMID and REVLIMID and associated services; **(d)** to conduct data analyses regarding the use of THALOMID and REVLIMID; **(e)** to comply with applicable laws.

The above information is stored on a computer in Australia and in the United States of America (USA) and will be subjected to backups, for security reasons, in Switzerland; therefore, this information will be exchanged between Australia, the USA and Switzerland.

If I object to the processing of my personal and medical data, no new information will be collected and added to the database. The data already gathered may still be used in accordance with the terms contained in this informed consent form. To exercise these rights, I can contact the Celgene Risk Management Centre, 0800 526 529 (select option 1). Such refusal constitutes a refusal to participate in the *i-access* program, and will affect my ability to receive THALOMID or REVLIMID.

I agree with these conditions and agree that my doctor can initiate my treatment with THALOMID or REVLIMID. I also provide consent for other prescribers to access my information for the purpose of treating my disease.

I agree to abide by the requirements of the *i-access* program in order for my doctor to begin my treatment with THALOMID or REVLIMID.

Name of patient/authorised representative
(strike out whichever does not apply)

X

Signature of patient/authorised representative
(strike out whichever does not apply)

Date

Fax both pages of this form to Celgene Australia Pty Ltd 0800 444 259

Criteria for women of non–childbearing potential

A female patient or a female partner of a male patient is considered to have childbearing potential unless she meets at least one of the following criteria:

- age ≥ 50 years and naturally amenorrhoeic for ≥ 1 year*
- premature ovarian failure confirmed by a specialist gynaecologist
- previous bilateral salpingo-oophorectomy, or hysterectomy
- XY genotype, Turner syndrome, uterine agenesis

*Amenorrhoea following cancer therapy does not rule out childbearing potential.

Patient consent form

Patient's name (please print) _____ Date _____

Patient/authorised representative: please read carefully and initial inside the box, next to the questions that apply to you, provided you agree with the statement.

ALL PATIENTS		
1.	I understand that birth defects may occur with the use of THALOMID (thalidomide) or REVLIMID (lenalidomide). I have been warned by my doctor that any unborn baby may have birth defects and can even die if a female is pregnant or becomes pregnant while taking THALOMID (thalidomide) or REVLIMID (lenalidomide).	Initial
2.	I understand that THALOMID (thalidomide) or REVLIMID (lenalidomide) will be prescribed ONLY for me. I must not share it with ANYONE, even someone who has similar symptoms to mine. It must be kept out of the reach of children and should NEVER be given to women who are able to have children.	Initial
3.	I have read the THALOMID (thalidomide) or REVLIMID (lenalidomide) patient brochure. I understand the contents, including other possible health problems or 'side-effects' from THALOMID (thalidomide) or REVLIMID (lenalidomide). I know that I cannot donate blood or sperm while taking THALOMID (thalidomide) or REVLIMID (lenalidomide) or for 4 weeks after stopping THALOMID (thalidomide) or REVLIMID (lenalidomide).	Initial
4.	My doctor has answered any questions I have asked.	Initial

WOMEN OF CHILDBEARING POTENTIAL ONLY		
5.	I understand that I must not take THALOMID (thalidomide) or REVLIMID (lenalidomide) if I am pregnant, am breastfeeding a baby, or am able to get pregnant and am not using a required method of birth control (contraception).*	Initial
6.	I understand that if I am able to become pregnant, am less than 50 years of age and/or my periods have stopped due to treatment of my disease, I must use at least one highly effective method of birth control (contraception).*	Initial
7.	I know that I must have a pregnancy test done by my doctor when being prescribed THALOMID (thalidomide) or REVLIMID (lenalidomide), or in the 3 days prior to seeing the doctor, even if I have not had my period due to treatment of my disease. I must have been using effective contraception for at least 4 weeks prior to the test. Further pregnancy tests must be done every 4 weeks while I am on THALOMID (thalidomide) or REVLIMID (lenalidomide) therapy.*	Initial
8.	I know that I must immediately stop taking THALOMID (thalidomide) or REVLIMID (lenalidomide) and inform my doctor if I become pregnant while taking the drug, or if I miss my menstrual period, experience unusual menstrual bleeding, stop using birth control, or think, FOR ANY REASON, that I may be pregnant.	Initial
9.	I am not pregnant, nor will I try to become pregnant for at least 4 weeks after I have completely finished taking THALOMID (thalidomide) or REVLIMID (lenalidomide).	Initial

WOMEN NOT OF CHILDBEARING POTENTIAL ONLY		
10.	I certify that I am not of childbearing potential as I am ≥ 50 years of age and have been in a natural menopause for at least 12 months (been through the changes of life) or have had my uterus/womb completely removed (hysterectomy) or have had both of my ovaries removed (bilateral oophorectomy).	Initial

MALES ONLY		
11.	I have been told by my doctor that I must NEVER have unprotected sexual contact with a woman who is pregnant or can become pregnant. As THALOMID (thalidomide) or REVLIMID (lenalidomide) is present in semen, my doctor has explained that I must either completely abstain from sexual contact with women who are pregnant or able to become pregnant, or I must use a latex condom EVERY TIME I engage in any sexual contact with women who are pregnant or may become pregnant while I am taking THALOMID (thalidomide) or REVLIMID (lenalidomide) and for 4 weeks after I stop taking the drug, even if I have had a successful vasectomy.	Initial
12.	I know that I must inform my doctor if I have unprotected sexual contact with a woman who can become pregnant, or if I think, FOR ANY REASON, that my sexual partner may be pregnant.	Initial

*Prescribers please refer to THALOMID (thalidomide) or REVLIMID (lenalidomide) New Zealand approved Data Sheet for details of requirements for pregnancy testing, contraception and determination of childbearing potential.

Please ensure you retain a copy of this form for your records. Upon signing this consent form, the patient has the right to obtain a copy.

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