

POMALIDOMIDE CIPLA RISK MANAGEMENT PROGRAMME TREATMENT INITIATION FORM

Prior to the initiation of **POMALIDOMIDE CIPLA** treatment, this form must be completed and signed by the prescriber and patient. Original form to be retained with the patient's medical records and a copy provided to the patient. The aim of this form is to protect patients and any unborn child by ensuring that patients understand the risk of teratogenicity associated with the use of **POMALIDOMIDE CIPLA**.

Patient Details

Tick only one:	<input type="checkbox"/>	New patient	<input type="checkbox"/>	Risk categorisation of registered patient changed
Patient Name:			National ID/Passport Number: (Used as unique patient identifier)	
Date of Birth: DD/MM/YYYY				
The patient will receive POMALIDOMIDE CIPLA to treat:	<input type="checkbox"/>	Relapsed Multiple Myeloma	<input type="checkbox"/>	Refractory Multiple Myeloma
	<input type="checkbox"/>		<input type="checkbox"/>	Other (please specify)
Risk Category of Patient (tick one): (Refer to <i>Healthcare Professional Information Brochure</i> for criteria)				
<input type="checkbox"/>	Female of Childbearing Potential	<input type="checkbox"/>	Female Not of Childbearing Potential	<input type="checkbox"/>
				Male

Mandatory for all patients to complete

- My doctor has explained the possible risks and benefits associated with **POMALIDOMIDE CIPLA**. I have had the opportunity to ask questions and I have understood the answers provided to me.
- I have received, read and understood the **Cipla Risk Management Support Programme Patient Information Brochure**.
- I understand that **POMALIDOMIDE CIPLA** has been prescribed for me personally and that I should not share it with any other person. I should store **POMALIDOMIDE CIPLA** out of the reach of children.
- I will return any unused capsules to my pharmacist/doctor.
- I will not donate blood during treatment and for 4 weeks after termination of treatment.

Date: DD/MM/YYYY

Signature of Patient

To be completed by female patients of non-child childbearing potential

- I understand the risks associated with **POMALIDOMIDE CIPLA**.
- I declare that it has been confirmed by a gynaecologist that I am of non-childbearing potential.
- I understand that **POMALIDOMIDE CIPLA** has been prescribed for me personally and that I should not share it with any other person.

Date: DD/MM/YYYY

Signature of Patient

To be completed by female patients of childbearing potential

- I understand that **POMALIDOMIDE CIPLA** is expected to be harmful to an unborn child.
- I will use two methods of effective contraception for four (4) weeks before starting treatment, during treatment interruption, throughout the entire duration of treatment and for four (4) weeks after the end of treatment.
- If I will not use two methods of contraception as stated above, I confirm that I will not engage in any sexual activity.
- Even if I do not experience monthly menstruation during treatment, I will still comply with the above contraceptive requirements.
- I agree to undergo pregnancy testing at 4 weekly intervals unless it has been confirmed by a gynaecologist that I am unable to become pregnant.
- In the event that I do become pregnant during treatment (or in the 4 weeks after stopping treatment) I will stop treatment with **POMALIDOMIDE CIPLA** and seek advice from my doctor immediately.

Date: DD/MM/YYYY

Signature of Patient

To be completed by male patients

- I understand that **POMALIDOMIDE CIPLA** is expected to be harmful to an unborn child.
- I agree to use condoms (even if I have had a vasectomy) throughout treatment duration, during dose interruption, and for four (4) weeks after termination of treatment if my partner is of childbearing potential not using effective contraception, or if my partner is pregnant.
- If my partner were to become pregnant during my treatment with **POMALIDOMIDE CIPLA**, I will advise her to seek

Date: DD/MM/YYYY

Signature of Patient

To be completed by prescriber

I confirm that I have explained the potential benefits and risks of **POMALIDOMIDE CIPLA** to the patient including the need to comply with the **Cipla Risk Management Support Programme**.

Prescriber Name

Date: DD/MM/YYYY

Signature

Protection of Personal Information Act (POPIA):

Cipla (herein referred to as, "we", "our", "us", "company", "responsible party") is committed to protect the privacy and security of your personal data that we process. The purpose of this notice is to inform you about our use of the data and/or personal information we collect from you.

As a responsible party, we need to keep and process your personal information for meeting legal obligations and compliance requirements as provided under the Applicable law, and for other customary business purposes. Without your personal information, **POMALIDOMIDE CIPLA** may not be prescribed ("purposes").

We may process the following categories of personal information about you depending on our relationship with you:

- Personal details including but not limited to name, title, addresses, post code, telephone numbers, mobile number, personal/corporate email addresses, date and place of birth, gender, age, insurance policy details, occupation, signatures.
- Medical information including but not limited to health, injury details, blood group, disability details, any specific medical condition, health and sickness records/medical certificates.
- Personal information including but not limited to race, ethnicity, religion, political opinions, philosophical beliefs, or sexual orientation.

We will only use your personal information for the purposes for which we collected it. We will keep and use it to enable us to run the business and manage our relationship with you effectively, lawfully, and appropriately, whilst you are associated with us, and after our association ends. If you fail to provide this data, we may not be able to fulfil our contractual obligation, or we may be prevented from complying with our legal obligations. It is important that the personal information you provide to us is accurate and current. Please keep us informed if your personal information changes during your working relationship with us.

We require your consent to obtain and use your personal information, and you may withdraw your consent at any time by notifying us in writing. We will maintain your data on our records for as long as we have your consent to do so. You can also request us to stop using your personal information at any time through withdrawal of your consent directed to us in writing at the following email address: ciplasa.rmp@cipla.com

POPIA Consent:

I, the undersigned confirm that I have read and understood the terms of POPI Act requirements as stated above and do hereby consent that Cipla may collect and process my personal information for the reasons mentioned above.

Prescriber Name	Date: DD/MM/YYYY	Signature
Patient Name	Date: DD/MM/YYYY	Signature

We may share your personal information with third parties, other Cipla entities and internal group companies. We require third parties and other entities to respect the security of your data and to treat it in accordance with our instructions, and in a way that is consistent with chapter 9 of POPI Act. This information transfer is permitted under Chapter 9, Section 72 of POPI Act which authorises the access seeker (known as the responsible party) permission to transfer the information across foreign borders in the following circumstances:

- the person receiving the information (outside of the Republic), must be governed by laws, binding corporate rules, binding agreements or memorandum of understanding between two public bodies which provide an adequate level of protection; or
- you must consent to the transfer; or
- the transfer must be necessary for:
 - the performance of a contract between you and the Responsible Party, or for the implementation of pre-contractual measures taken in response to your request;
 - the conclusion or performance of a contract concluded in your interest between the Responsible Party and a third party; or
 - the transfer is for your benefit and:
 - it is not reasonably practicable to obtain your consent for that transfer; and
 - if it were reasonably practicable to obtain such consent, you would provide it.

We will not share your personal information with any other third parties or use your personal information for any purpose other than described above. The information collected by us that you provide will not be used to make any automated decisions about you.

We have put in place measures to protect the security of your data. We have established procedures to deal with any suspected data security breach and will notify you and any applicable regulator of a suspected breach where we are legally required to do so.

If you are uncertain about this form, or the manner in which your information will be processed, please contact our Drug Safety team at this email address: drugsafetysa@cipla.com.

[S4] Reg. No. 56/32/0540, 56/32/0541, 56/32/0542, 56/32/0543 Pomalidomide Cipla 1 / 2 / 3 / 4 mg. Each hard gelatin capsule contains 1 mg; 2 mg; 3 mg; 4 mg of Pomalidomide. For full prescribing information, refer to the Professional Information approved by the medicines regulatory authority. CIPLA MEDPRO (PTY) LTD. Co. Reg. No. 1995/004182/07. Building 9, Parc du Cap, Mispel Street, Bellville, 7530, RSA. Website: www.cipla.co.za Customer Care: 080 222 6662. [587832454b]