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RISK MANAGEMENT PROGRAM FOR LENALIDOMIDE CIPLA TREATMENT INITIATION FORM

Prior to the initiation of **LENALIDOMIDE CIPLA** treatment, this form must be completed by the prescribing physician with every new patient. The original form should be retained with the patient's medical records and a copy provided to the patient. The aim of the *Treatment Initiation Form* is to protect patients and any possible unborn child by ensuring that patients are fully informed of and understand the risk of teratogenicity associated with the use of **LENALIDOMIDE CIPLA**.

With this *Treatment Initiation Form*, the prescribing physician confirms individual counselling for the stated below patient, receiving **LENALIDOMIDE CIPLA**.

Please complete in block letters.

Patient Details					
Tick only one:		New patient		Risk categorisation of registered patient changed	
Patient Name:					
Date of Birth: DD/MM/YYYY					
The patient will receive **LENALIDOMIDE CIPLA** to treat:		Multiple Myeloma		Other (please specify)	
Risk Category of Patient (tick one): (Refer to *Healthcare Professional Information Brochure* for criteria)					
	Female of Childbearing Potential		Female Not of Childbearing Potential		Male

I confirm that I, _____ [Patient Name and Surname], have received and understood the information provided to me on the potential benefits and risks of taking **LENALIDOMIDE CIPLA** and that this has been explained to me by Dr. _____ [Name and Surname].

In particular, I confirm that:

SECTION A (mandatory **for all patients**)

- My doctor has explained to me, and I understand the possible risks and the possible benefits associated with **LENALIDOMIDE CIPLA**. I have had the opportunity to ask questions and I have understood the answers provided to those questions.
- I have received, read and understood the ***Cipla Risk Management Support Programme*** *Patient Information Brochure*.
- I understand that **LENALIDOMIDE CIPLA** has been prescribed for me personally and that I should not share it with any other person even if they have the same condition as me. I should store **LENALIDOMIDE 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.

Place	Date: DD/MM/YYYY	Signature of Patient

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SECTION B (to be completed by **female patients of childbearing potential** as determined by prescriber)

- I understand that **LENALIDOMIDE CIPLA** is expected to be harmful to an unborn child.
- I will use two methods of effective contraception for 4 weeks before starting treatment, during treatment interruption, throughout the entire duration of treatment and for 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.
- I will attempt to take my prescription to the pharmacist for dispensing within one working day from when my doctor provides me with the prescription.
- In the event that I do become pregnant during treatment (or in the 4 weeks after stopping treatment) I will stop treatment with **LENALIDOMIDE CIPLA** and seek advice from my doctor immediately.

Place	Date: DD/MM/YYYY	Signature of Patient

SECTION C (to be completed by **male patients**)

- I understand that **LENALIDOMIDE 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 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 **LENALIDOMIDE CIPLA**, I will advise her to seek medical advice immediately.

Place	Date: DD/MM/YYYY	Signature of Patient

SECTION D (**prescriber**)

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

The following material has been provided to the patient (please tick box):

☐ ***Cipla Risk Management Support Programme*** *Patient Information Brochure*

Prescriber Name	Hospital/Centre	Signature

Important: A copy of this form needs to be provided to the patient and a copy needs to be retained in patient records.

D	D	M	M	Y	Y	Y	Y

S4 Reg. No. 55/32/0295.294, 53/32/0374.371, 0375.372, 0376.373. Lenalidomide Cipla 5 / 10 / 15 / 25 mg. Each hard gelatin capsule contains 5 mg; 10 mg; 15 mg; 25 mg of lenalidomide.
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]