Lenalidomide is present in the semen of patients receiving the drug. Therefore, males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking Lenalidomide and for up to 28 days after discontinuing Lenalidomide, even if they have undergone a successful vasectomy. Male patients taking Lenalidomide must not donate sperm.

Blood Donation
Patients must not donate blood during treatment with Lenalidomide and for 1 month following discontinuation of the drug because the blood might be given to a pregnant female patient whose fetus must not be exposed to Lenalidomide.

Hematologic Toxicity
Lenalidomide can cause significant neutropenia and thrombocytopenia. Patients taking Lenalidomide for MDS should have their complete blood counts monitored weekly for the first 8 weeks and at least monthly thereafter. Patients taking Lenalidomide for MM should have their complete blood counts monitored every 2 weeks for the first 12 weeks and then monthly thereafter. Patients taking Lenalidomide for MCL should have their complete blood counts monitored weekly for the first cycle (28 days), every 2 weeks during cycles 2-4, and then monthly thereafter. Patients may require dose interruption and/or dose reduction. Grade 3 or 4 hematologic toxicity was seen in 80% of patients enrolled in the MDS study. In the 48% of patients who developed Grade 3 or 4 neutropenia, the median time to onset was 42 days (range, 14-411 days), and the median time to documented recovery was 17 days (range, 2-170 days). In the 54% of patients who developed Grade 3 or 4 thrombocytopenia, the median time to onset was 28 days (range, 8-290 days), and the median time to documented recovery was 22 days (range, 5-224 days. In the pooled MM trials Grade 3 and 4 hematologic toxicities were more frequent in patients treated with the combination of Lenalidomide and dexamethasone than in patients treated with dexamethasone alone. In the MCL trial, Grade 3 or 4 neutropenia was reported in 43% of the patients. Grade 3 or 4 thrombocytopenia was reported in 28% of the patients.

Venous and Arterial Thromboembolism
Venous thromboembolic events (deep venous thrombosis and pulmonary embolism) and arterial thromboses are increased in patients treated with Lenalidomide. A significantly increased risk of DVT (7.4%) and of PE (3.7%) occurred in patients with multiple myeloma who were treated with Lenalidomide and dexamethasone therapy compared to patients treated in the placebo and dexamethasone group (3.1% and 0.9%) in clinical trials with varying use of anticoagulant therapies. Myocardial infarction (1.7%) and stroke (CVA) (2.3%) are increased in patients with multiple myeloma who were treated with Lenalidomide and dexamethasone therapy compared to patients treated with placebo and dexamethasone (0.6%, and 0.9%) in clinical trials. Patients with known risk factors, including prior thrombosis, may be at greater risk and actions should be taken to try to minimize all modifiable factors (e.g. hyperlipidemia, hypertension, smoking)
In controlled clinical trials that did not use concomitant thromboprophylaxis, 21.5% overall thrombotic events (Standardized MedDRA Query Embolic and Thrombotic events) occurred in patients with refractory and relapsed multiple myeloma who were treated with Lenalidomide and dexamethasone compared to 8.3% thrombosis in patients treated with placebo and dexamethasone. The median time to first thrombosis event was 2.7 months. Thromboprophylaxis is recommended. The regimen of thromboprophylaxis should be based on an assessment of the patient's underlying risks. Instruct patients to report immediately any signs and symptoms suggestive of thrombotic events. ESAs and estrogens may further increase the risk of thrombosis and their use should be based on a benefit-risk decision in patients receiving Lenalidomide.

Hepatotoxicity
Hepatic failure, including fatal cases, has occurred in patients treated with lenalidomide in combination with dexamethasone. In clinical trials, 15% of patients experienced hepatotoxicity (with hepatocellular, cholestatic and mixed characteristics); 2% of patients with multiple myeloma and 1% of patients with myelodysplasia had serious hepatotoxicity events. The mechanism of drug-induced hepatotoxicity is unknown. Pre-existing viral liver disease, elevated baseline liver enzymes, and concomitant medications may be risk factors. Monitor liver enzymes periodically. Stop Lenalidomide upon elevation of liver enzymes. After return to baseline values, treatment at a lower dose may be considered.

Allergic Reactions
Angioedema and serious dermatologic reactions including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported. These events can be fatal. Patients with a prior history of Grade 4 rash associated with thalidomide treatment should not receive Lenalidomide. Lenalidomide interruption or discontinuation should be considered for Grade 2-3 skin rash. Lenalidomide must be discontinued for angioedema, Grade 4 rash, exfoliative or bullous rash, or if SJS or TEN is suspected and should not be resumed following discontinuation for these reactions.
Lenalidomide capsules contain lactose. Risk-benefit of Lenalidomide treatment should be evaluated in patients with lactose intolerance.

Tumor Lysis Syndrome
Fatal instances of tumor lysis syndrome have been reported during treatment with lenalidomide. The patients at risk of tumor lysis syndrome are those with high tumor burden prior to treatment. These patients should be monitored closely and appropriate precautions taken.

PRECAUTIONS
Laboratory tests
A complete blood cell count (CBC) including white blood cell count with differential count , platelet count, haemoglobin should be performed weekly for the first 8 weeks of Lenalidomide treatment and monthly thereafter to monitor for cytopenias.
Carcinogenesis , Mutagenesis , Impairment of Fertility Carcinogenicity : Critical data not available

Mutagenesis : Lenalidomide does not induce mutation
Fertility : Animal studies did not reveal any parental toxicity and adverse effects on fertility. Reproductive effects of Lenalidomide have not been thoroughly assessed.
The structural similarity of Lenalidomide to Thalidomide , a known human teratogen , suggests a potential risk to the developing fetus.

OVERDOSE
Clinical data is not available.

HOW SUPPLIED
Mayoplast 5 – A HDPE bottle containing 30 capsules, packed in carton along with pack insert.
Mayoplast 10 - A HDPE bottle containing 30 capsules, packed in carton along with pack insert.
Mayoplast 25 - A HDPE bottle containing 30 capsules, packed in carton along with pack insert.

STORAGE
Store at a temperature not exceeding 30°C.
Protect from light & moisture.
Keep out of reach of children.

Manufactured by:
ADMAC LIFESCIENCES
(Dedicated Oncology Facility)
Plot No.107 A & 107 B, EPIP Phase-I,
Jharmajri, Baddi, Distt. Solan-174103 (H.P.), INDIA

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Scan for Batch Certificate

PRESCRIBING INFORMATION : For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Lenalidomide Capsules I.P. 5 mg, 10 mg and 25 mg

AMERICAN **Mayoplast** मेयोप्लास्ट

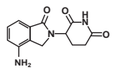
Warning : Lenalidomide should never be taken by pregnant women or women capable of becoming pregnant as even a single dose can cause severe birth defects or death to an unborn baby.

Mayoplast 5
Composition:
Each hard gelatin capsule contains :
Lenalidomide I.P. 5 mg
Excipients q.s
Approved colours used in empty capsule shell.

Mayoplast 10
Composition:
Each hard gelatin capsule contains :
Lenalidomide I.P. 10 mg
Excipients q.s
Approved colours used in empty capsule shell.

Mayoplast 25
Composition:
Each hard gelatin capsule contains :
Lenalidomide I.P. 25 mg
Excipients q.s
Approved colours used in empty capsule shell.

DESCRIPTION
Lenalidomide is an analogue of Thalidomide. It is Immunomodulatory agent with anti-angiogenic and anti-neoplastic properties.
The chemical name is 3-(4-amino-1,3-dihydro-1-oxo-2H- isoindol-2-yl) piperidine-2,6-dione and it has the following chemical structure :



The chemical formula for Lenalidomide is $C_{13}H_{13}N_3O_3$ and the gram molecular weight is 259.26062 g/mol.
Lenalidomide is an off-white to pale-yellow powder. It is soluble in organic solvent / water mixtures , and buffered aqueous solvents. Lenalidomide is more soluble in organic solvents and low pH solutions. Solubility was significantly lower in less acidic buffers, ranging from about 0.4 to 0.5 mg/ml.

CLINICAL PHARMACOLOGY
Mechanism of Actions
Lenalidomide is an analogue of Thalidomide. It is Immunomodulatory agent with anti-angiogenic and anti-neoplastic properties. Lenalidomide inhibits inhibits proliferation and induces apoptosis of certain hematopoietic tumor cells including multiple myeloma, mantle cell lymphoma, and del (5q) myelodysplastic syndromes in vitro. Lenalidomide causes a delay in tumor growth in some in vivo nonclinical hematopoietic tumor models including multiple myeloma. Immunomodulatory properties of lenalidomide include activation of T cells and natural killer (NK) cells, increased numbers of NKT cells, and inhibition of pro-inflammatory cytokines (e.g., TNF-α and IL-6) by monocytes.

PHARMACOKINETICS
Absorption
Lenalidomide is rapidly absorbed following oral administration. Following single and multiple doses of Lenalidomide in patients with MM or MDS the maximum plasma concentrations occurred between 0.5 and 6 hours post-dose. The single and multiple dose pharmacokinetic disposition of lenalidomide is linear with AUC and C_{max} values increasing proportionally with dose. Multiple dosing at the recommended dose-regimen does not result in drug accumulation.
Systemic exposure (AUC) of lenalidomide in MM and MDS patients with normal or mild renal function (CLcr ≥ 60 mL/min) is approximately 60% higher as compared to young healthy male subjects.
Administration of a single 25 mg dose of Lenalidomide with a high-fat meal in healthy subjects reduces the extent of absorption, with an approximate 20% decrease in AUC and 50% decrease in C_{max}. In the trials where the efficacy and safety were established for Lenalidomide , the drug was administered without regard to food intake. Lenalidomide can be administered with or without food.

Distribution
In vitro (14C)-lenalidomide binding to plasma proteins is approximately 30%.
Metabolism
Lenalidomide -undergoes limited metabolism. Unchanged lenalidomide is the predominant circulating component in humans. Two identified metabolites are hydroxy-lenalidomide and N-acetyl-lenalidomide; each constitutes less than 5% of parent levels in circulation.
Elimination
Elimination is primarily renal. Following a single oral administration of (14C)-lenalidomide (25 mg) to healthy subjects, approximately 90% and 4% of the radioactive dose is eliminated within ten days in urine and feces, respectively. Approximately 82% of the radioactive dose is excreted as lenalidomide in the urine within 24 hours. Hydroxy-lenalidomide and N-acetyl-lenalidomide represent 4.59% and 1.83% of the excreted dose, respectively. The renal clearance of lenalidomide exceeds the glomerular filtration rate.
The mean half-life of lenalidomide is 3 hours in healthy subjects and 3 to 5 hours in patients with MM, MDS or MCL.

Specific Populations
Pregnancy
Pregnancy Category X [see Boxed Warnings and Contraindications (4.1)]
Lenalidomide can cause embryo-fetal harm when administered to a pregnant female and is contraindicated during pregnancy. Lenalidomide is a thalidomide analogue.Thalidomide is a human teratogen, inducing a high frequency of severe and life-threatening birth defects such as amelia (absence of limbs), phocomelia (short limbs), hypoplasticity of the bones, absence of bones, external ear abnormalities (including anotia, micropinna, small or absent external auditory canals), facial palsy, eye abnormalities (anophthalmos, microphthalmos), and congenital heart defects. Alimentary tract, urinary tract, and genital malformations have also been documented and mortality at or shortly after birth has been reported in about 40% of infants.Lenalidomide caused thalidomide-type limb defects in monkey offspring. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.If pregnancy does occur during treatment, immediately discontinue the drug. Under these conditions, refer patient to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Nursing mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants from lenalidomide, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Females of Reproductive Potential and Males
Lenalidomide can cause fetal harm when administered during pregnancy . Females of reproductive potential must avoid pregnancy 4 weeks before therapy, while taking Lenalidomide, during dose interruptions and for at least 4 weeks after completing therapy.
Females
Females of reproductive potential must commit either to abstain continuously from heterosexual sexual intercourse or to use two methods of reliable birth control simultaneously (one highly effective form of contraception – tubal ligation, IUD, hormonal (birth control pills, injections, hormonal patches, vaginal rings or implants) or partner's vasectomy and one additional effective contraceptive method – male latex or synthetic condom, diaphragm or cervical cap. Contraception must begin 4 weeks prior to initiating treatment with Lenalidomide, during therapy, during dose interruptions and continuing for 4 weeks following discontinuation of Lenalidomide therapy. Reliable contraception is indicated even where there has been a history of infertility, unless due to hysterectomy. Females of reproductive potential should be referred to a qualified provider of contraceptive methods, if needed.
Females of reproductive potential must have 2 negative pregnancy tests before initiating Lenalidomide. The first test should be performed within 10-14 days, and the second test within 24 hours prior to prescribing Lenalidomide. Once treatment has started and during dose interruptions, pregnancy testing for females of reproductive potential should occur weekly during the first 4 weeks of use, then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks. Pregnancy testing and counselling should be performed if a patient misses her period or if there is any abnormality in her menstrual bleeding. Lenalidomide treatment must be discontinued during this evaluation.

Males
Lenalidomide is present in the semen of males who take Lenalidomide. Therefore, males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking Lenalidomide, during dose interruptions and for up to 28 days after discontinuing Lenalidomide, even if they have undergone a successful vasectomy. Male patients taking Lenalidomide must not donate sperm

Patients with Renal Impairment:
The pharmacokinetics of lenalidomide were studied in patients with renal impairment due to nonmalignant conditions. In this study, 5 patients with mild renal impairment (creatinine clearance 57-74 mL/min), 6 patients with moderate renal impairment (creatinine clearance 33-46 mL/min), 6 patients with severe renal impairment (creatinine clearance 17-29 mL/min), and 6 patients with end stage renal disease requiring dialysis were administered a single oral 25-mg dose of Lenalidomide. As a control group comparator, 7 healthy subjects of similar age with normal renal function (creatinine clearance 83-145 mL/min) were also administered a single oral 25-mg dose of Lenalidomide. As creatinine clearance decreased from mild to severe impairment, half-life increased and drug clearance decreased linearly. Patients with moderate and severe renal impairment had a 3-fold increase in half-life and a 66% to 75% decrease in drug clearance compared to healthy subjects. Patients on hemodialysis (n=6) given a single, 25-mg dose of lenalidomide has an approximate 4.5-fold increase in half-life and an 80% decrease in drug clearance compared to healthy subjects. Approximately 40% of the administered dose was removed from the body during a single dialysis session.
In MM patients, those patients with mild renal impairment had an AUC 56% greater than those with normal renal function.Adjustment of the starting dose of Lenalidomide is recommended in patients with moderate or severe (CLcr < 60 mL/min) renal impairment and in patients on dialysis.

Pediatric
Clinical data not available in patients below the age of 18 years

Gender
The effects of gender on the pharmacokinetics of Lenalidomide have not been studied

Race
Clinical data not available

INDICATIONS AND USAGE
Lenalidomide is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
Lenalidomide in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

DOSAGE AND ADMINISTRATION
Multiple Myeloma

When Platelets	Recommended Course
Fall to <30,000/mcL	Interrupt **Lenalidomide** treatment, follow CBC weekly
Return to ≥30,000/mcL	Restart **Lenalidomide** at 15 mg daily
For each subsequent drop <30,000/mcL	Interrupt **Lenalidomide** treatment
Return to ≥30,000/mcL	Resume **Lenalidomide** at 5 mg less than the previous dose. Do not dose below 5 mg

Absolute Neutrophil counts (ANC)
Neutropenia in MM

When Neutrophils	Recommended Course
Fall to <1000/mcL	Interrupt **Lenalidomide** treatment, add G-CSF, follow CBC weekly
Return to ≥1,000/mcL and neutropenia is the only toxicity	Resume **Lenalidomide** at 25 mg daily
Return to ≥1,000/mcL and if other toxicity	Resume **Lenalidomide** at 15 mg daily'
For each subsequent drop <1,000/mcL	Interrupt **Lenalidomide** treatment
Return to ≥1,000/mcL	Resume **Lenalidomide** at 5 mg less than the previous dose. Do not dose below 5 mg daily

Other Grade 3 / 4 Toxicities in MM
For other Grade 3/4 toxicities judged to be related to **Lenalidomide**, hold treatment and restart at the physician's discretion at next lower dose level when toxicity has resolved to ≤ Grade 2.

Myelodysplastic Syndromes
The recommended starting dose of **Lenalidomide** is 10 mg daily with water.
Dose Adjustments for Hematologic Toxicities During MDS Treatment
Platelet counts
Patients who are dosed initially a 10mg and who experience thrombocytopenia should have their dosage adjusted as follows.
Thrombocytopenia in MDS

Time to Thrombocytopenia	Baseline value	When Platelets	Recommended Course
Within 4 week of starting therapy with 10 mg daily	≥1,000/mcL <100,000/mcL	Fall to <50,000/mcL Return to ≥50,000/mcL Fall to 50% of the baseline If baseline ≥60,000/mcL and returns to ≥50,000/mcL If baseline <60,000/mcL and returns to ≥30,000/mcL	Interrupt Lenalidomide treatment Resume Lenalidomide 5 mg daily Interrupt Lenalidomide treatment Resume Lenalidomide at 5 mg daily Resume Lenalidomide at 5 mg daily
After 4 weeks of starting treatment with 10mg daily		<30,000/mcLor <50,000/mcL with platelet transfusions Return to ≥30,000/mcL (without hemostatic failure)	Interrupt Lenalidomide treatment Resume Lenalidomide at 5 mg daily
While on treatment with 5 mg daily		<30,000/mcLor <50,000/mcL with platelet transfusions Return to ≥30,000/mcL (without hemostatic failure)	Interrupt Lenalidomide treatment Resume Lenalidomide at 5 mg over other day.

Neutrophil counts : Patients who are dosed initially at 10mg and experience Neutropenia should have their dosage adjusted as follows .
Neutropenia in MDS : If Neutropenia develops within 4 weeks of starting treatment at 10mg daily in MDS

Time to Neutropenia	Baseline ANC	When Neutrophils	Recommended Course
Within 4 weeks of starting therapy with 10mg daily	≥1,000/mcL <1,000/mcL	Fall to <750/mcL Return to ≥1,000/mcL Fall to <500/mcL Return to ≥500/mcL	Interrupt Lenalidomide therapy Resume Lenalidomide 5 mg Interrupt Lenalidomide therapy Resume Lenalidomide 5 mg
After 4 weeks of starting treatment with 10mg daily		<500/mcL for ≥7 days or <500/mcL associated with fever (≥38.5°C) Return to ≥500/mcL	Interrupt Lenalidomide therapy. Resume Lenalidomide 5 mg
While on treatment with 5mg daily		<500/mcL for ≥7 days or <500/mcL associated with fever (≥38.5°C) Return to ≥500/mcL	Interrupt Lenalidomide therapy. Resume Lenalidomide at 5 mg over other day.

Starting Dose for Renal Impairment in MM , MDS.
Since Lenalidomide is primarily excreted unchanged by the kidney, adjustments to the starting dose of Lenalidomide are recommended to provide appropriate drug exposure in patients with moderate or severe renal impairment and in patients on dialysis. Based on a pharmacokinetic study in patients with renal impairment due to non-malignant conditions, Leanlidomide starting dose adjustment is recommended for patients with CLcr < 60 mL/min. Non-dialysis patients with creatinine clearances less than 11 mL/min and dialysis patients with creatinine clearances less than 7 mL/min have not been studied. The recommendations for initial starting doses for patients with MM, MDS are as follows:

Starting Dose Adjustments for Patients with Renal Impairment in MM, MDS.

Category	Renal Function (Cockcroft-Gault)	Dose in MM or MCL	Dose in MDS
Moderate Renal Impairment	CLcr 30-60 mL/min	10mg Every 24 hours	5mg Every 24 hours
Severe Renal Impairment	CLcr <30 mL/min (requiring dialysis)	15mg Every 48 hours	2.5mg Every 24 hours
Severe Renal Impairment	CLcr <30 mL/min (requiring dialysis)	5mg Once daily. On dialysis days, administer the dose following dialysis	2.5mg Once daily. On dialysis days, administer the dose following dialysis.

The recommended starting dose of **Lenalidomide** is 25 mg once daily on Days 1-21 of repeated 28-day cycles. The recommended dose of dexamethasone is 40 mg once daily on Days 1-4, 9-12, and 17-20 of each 28-day cycle for the first 4 cycles of therapy and then 40 mg once daily orally on Days 1–4 every 28 days. Treatment is continued or modified based upon clinical and laboratory findings.
Dose Adjustments for Hematologic Toxicities During Multiple Myeloma Treatment
Dose modification guidelines, as summarized below, are recommended to manage Grade 3 or 4 neutropenia or thrombocytopenia or other Grade 3 or 4 toxicity judged to be related to **Lenalidomide.**
Platelet counts
Thrombocytopenia in MM
After initiation of lenalidomide therapy, subsequent lenalidomide dose modification is based on individual patient treatment tolerance.

ADVERSE EVENTS
Adverse events reported in 5% of the Lenalidomide capsules treated patients in del 5q MDS clinical study include
Skin and subcutaneous tissue disorders : Pruritus , Rash , dry skin , contusion, night sweats. Ecchymosis, Erythema
Gastrointestinal disorders : Diarrhea , Constipation, Nausea , abdominal pain, dry mouth, loose stools
Respiratory, thoracic and mediastinal disorders: Nasopharyngitis, cough, Dyspnea, Pharyngitis, Epistaxis
General disorders and administration site conditions : Fatigue, pyrexia, edema, asthenia, pain, rigors
Musculoskeletal and connective tissue disorders : Arthralgia, back pain, muscle cramp, myalgia.
Nervous system disorders : Dizziness, headache, hypoesthesia, dysgeusia, peripheral neuropathy.
Infections and infestations : Upper respiratory tract infection, pneumonia, UTI, sinusitis
Metabolism and nutrition disorders: Hypokalemia, anorexia, hypomagnesemia
Psychiatric disorders: Insomnia, depression
Renal and urinary disorders: Dysuria
Vascular system disorders: Hypertension
Endocrine disorders: Acquired hypothyroidism
Most frequently observed grade 3 & 4 advese events include : Neutropenia, Thrombocytopenia , rash , anemia , pneumonia , leucopenia.

DRUG INTERACTIONS
Lenalidomide is neither metabolized by nor inhibits or induces the cytochrome P450 pathway suggesting that lenalidomide is not likely to cause or be subject to P450-based metabolic drug interactions.
When digoxin was co-administered with multiple doses of Lenalidomide (10 mg/day) the digoxin Cmax and AUC0-∞ were increased by 14%. Periodic monitoring of digoxin plasma levels, in accordance with clinical judgment and based on standard clinical practice in patients receiving this medication, is recommended during administration of Lenalidomide.

CONTRAINDICATIONS
Pregnancy
Lenalidomide Capsules can cause fetal harm when administered to a pregnant female. Limb abnormalities were seen in the offspring of monkeys that were dosed with lenalidomide during organogenesis. This effect was seen at all doses tested. Due to the results of this developmental monkey study, and lenalidomide's structural similarities to thalidomide, a known human teratogen, lenalidomide is contraindicated in females who are pregnant . If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.
Hypersensitivity
Lenalidomide capsules is contraindicated in patients who have demonstrated hypersensitivity (e.g angioedema , Stevens-Hohnson syndrome , toxic epidermal necrolysis) to lenalidomide.

WARNINGS
Embryo-Fetal Toxicity
Lenalidomide Capsules is a thalidomide analogue and is contraindicated for use during pregnancy . Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide is used during pregnancy, it may cause birth defects or embryo-fetal death .

Females of Reproductive Potential
Females of reproductive potential must avoid pregnancy for at least 4 weeks before beginning Lenalidomide therapy , during therapy, during dose interruptions and for at least 4 weeks after completing therapy. Females must commit either to abstain continuously from heterosexual sexual intercourse or to use two methods of reliable birth control, beginning 4 weeks prior to initiating treatment with Lenalidomide, during therapy, during dose interruptions and continuing for 4 weeks following discontinuation of Lenalidomide therapy.
Two negative pregnancy tests must be obtained prior to initiating therapy. The first test should be performed within 10-14 days and the second test within 24 hours prior to prescribing Lenalidomide therapy and then weekly during the first month, then monthly thereafter in women with regular menstrual cycles or every 2 weeks in women with irregular menstrual cycles

Males