

Taking this medicine

To remove the capsule from the blister:



press only one end of the capsule out to push it through the foil



do not put pressure on the centre of the capsule, as this can cause it to break.



Duration of the treatment with Lenalidomide Mylan

Lenalidomide Mylan is taken in treatment cycles, each cycle lasting 21 or 28 days (see above 'Treatment cycle'). You should continue the cycles of treatment until your doctor tells you to stop.

If you take more Lenalidomide Mylan than you should

If you take more Lenalidomide Mylan than was prescribed, tell your doctor immediately.

If you forget to take Lenalidomide Mylan

If you forget to take Lenalidomide Mylan at your regular time and:

- less than 12 hours have passed – take your capsule immediately.
- more than 12 hours have passed – do not take your capsule. Take your next capsule at the usual time the next day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Lenalidomide Mylan can cause side effects, although not everybody gets them.

Stop taking Lenalidomide Mylan and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Hives, rashes, swelling of eyes, mouth or face, difficulty breathing, or itching, which may be symptoms of serious types of allergic reactions called angioedema and anaphylactic reaction.
- A serious allergic reaction that may begin as a rash in one area but spread with extensive loss of skin over the whole body (Stevens-Johnson syndrome and/or toxic epidermal necrolysis).
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). See also section 2.

Tell your doctor straight away if you notice any of the following serious side effects:

- Fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection including within the bloodstream (sepsis)
- Bleeding or bruising in the absence of injury
- Chest pain or leg pain
- Shortness of breath
- Bone pain, muscle weakness, confusion or tiredness that might be due to high level of calcium in the blood.

Lenalidomide Mylan may reduce the number of white blood cells that fight infection and also the blood cells which help the blood to clot (platelets) which may lead to bleeding disorders such as nosebleeds and bruising.

Lenalidomide Mylan may also cause blood clots in the veins (thrombosis).

Other side effects

It is important to note that a small number of patients may develop additional types of cancer, and it is possible that this risk may be increased with Lenalidomide Mylan treatment. Therefore, your doctor should carefully evaluate the benefit and risk when you are prescribed Lenalidomide Mylan.

Very common side effects (may affect more than 1 in 10 people):

- A fall in the number of red blood cells which may cause anaemia leading to tiredness and weakness
- Rashes, itching
- Muscle cramps, muscle weakness, muscle pain, muscle aches, bone pain, joint pain, back pain, pain in the extremities
- Generalised swelling including swelling of your arms and legs
- Weakness, tiredness
- Fever and flu like symptoms including fever, muscle ache, headache, earache, cough and chills
- Numbness, tingling or burning sensation to the skin, pains in hands or feet, dizziness, tremor
- Decreased appetite, change in the way things taste
- Increase in pain, tumour size or redness around the tumour
- Weight loss
- Constipation, diarrhoea, nausea, vomiting, stomach pain, heartburn
- Low levels of potassium or calcium and/or sodium in the blood
- Thyroid functioning less than it should be
- Leg pain (which could be a symptom of thrombosis), chest pain or shortness of breath (which may be a symptom of blood clots in the lungs, called pulmonary embolism)
- Infections of all types, including infection of the sinuses that surround the nose, infection of the lung and the upper respiratory tract.
- Shortness of breath
- Blurred vision
- Clouding of your eye (cataract)
- Kidney problems which include kidneys not working properly or not being able to maintain normal function
- Abnormal liver test results
- Increase in liver test results
- Changes to a protein in the blood that can cause swelling of the arteries (vasculitis)
- Increases in your blood sugar level (diabetes)
- Decreases in your blood sugar levels
- Headache
- Nosebleed
- Dry skin
- Depression, mood change, difficulty sleeping

- Cough
- A fall in blood pressure
- A vague feeling of bodily discomfort, feeling bad
- Sore inflamed mouth, dry mouth
- Dehydration

Common side effects (may affect up to 1 in 10 people):

- Destruction of red blood cells (haemolytic anaemia)
- Certain types of skin tumour
- Bleeding of the gums, stomach, or bowels
- Increased blood pressure, slow, fast or irregular heart beat
- Increase in the amount of a substance which results from normal and abnormal breakdown of red blood cells
- Increase in a type of protein that indicates inflammation in body
- Darkening of your skin, discolouration of your skin resulting from bleeding underneath, typically caused by bruising, swelling of skin filled with blood, bruise
- Increase in uric acid in the blood
- Skin eruptions, redness of skin, cracking, flaking or peeling skin, hives
- Increased sweating, night sweats
- Difficulty swallowing, sore throat, difficulty with voice quality or voice changes
- Runny nose
- Production of much more or much less urine than usual or the inability to control when to urinate
- Passing blood in the urine
- Shortness of breath especially when lying down (which may be a symptom of heart failure)
- Difficulty getting an erection
- Stroke, fainting, vertigo (problem with your inner ear which leads to a feeling that everything is spinning), temporary loss of consciousness
- Chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick or vomiting, which may be symptoms of a heart attack (myocardial infarction)
- Muscle weakness, lack of energy
- Neck pain, chest pain
- Chills
- Joint swelling
- Bile flow from the liver slowed or blocked
- Low levels of phosphate or magnesium in the blood
- Difficulty speaking
- Liver injury
- Impaired balance, difficulty moving
- Deafness, ringing in the ears (tinnitus)
- Nerve pain, unpleasant abnormal sensation especially to touch
- An excess of iron in the body
- Thirst
- Confusion
- Toothache
- Fall which may result in injury

Uncommon side effects (may affect up to 1 in 100 people):

- Bleeding within the skull
- Circulatory problems
- Loss of vision
- Loss of sex drive (libido)
- Passing large amounts of urine with bone pain and weakness, which may be symptoms of a kidney disorder (Fanconi syndrome)
- Yellow pigmentation to the skin, mucus membrane or eyes (jaundice), pale coloured stools, dark coloured urine, skin itch, rash, pain or swelling of the stomach – these may be symptoms of injury to the liver (hepatic failure)
- Stomach pain, bloating, or diarrhoea, which may be symptoms of inflammation in the large intestine (called colitis or caecitis)
- Damage to the cells of the kidney (called renal tubular necrosis)
- Changes to the colour of your skin, sensitivity to sunlight
- Tumour lysis syndrome - metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the break-down products of dying cancer cells and may include the following: changes to blood chemistry; high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heart beat, seizures, and sometimes death.
- Increase in blood pressure within blood vessels that supply the lungs (pulmonary hypertension).

Not known side effects (frequency cannot be estimated from the available data):

- Sudden, or mild but worsening pain in the upper stomach and/or back, which remains for a few days, possibly accompanied by nausea, vomiting, fever and a rapid pulse – these symptoms may be due to inflammation of the pancreas.
- Wheezing, shortness of breath or a dry cough, which may be symptoms caused by inflammation of the tissue in the lungs.
- Rare cases of muscle breakdown (muscle pain, weakness or swelling) which can lead to kidney problems (rhabdomyolysis) have been observed, some of them when lenalidomide is administered with a statin (a type of cholesterol lowering medicines).
- A condition affecting the skin caused by inflammation of small blood vessels, along with pain in the joints and fever (leukocytoclastic vasculitis).
- Breakdown of the wall of the stomach or gut. This may lead to very serious infection. Tell your doctor if you have severe stomach pain, fever, nausea, vomiting, blood in your stool, or changes in bowel habits.
- Viral infections, including herpes zoster (also known as 'shingles', a viral disease that causes a painful skin rash with blisters) and recurrence of hepatitis B infection (which can cause yellowing of the skin and eyes, dark brown-coloured urine, right-sided stomach pain, fever and feeling nauseous or being sick).
- Rejection of solid organ transplant (such as kidney, heart).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lenalidomide Mylan

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the blister and on the carton after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use this medicine if you notice any damage or signs of tampering to the pack.
- Do not throw away any medicines via wastewater or household waste. Please return unused medicines to your pharmacist. These measures will help protect the environment.

6. Contents of the pack and other information

What Lenalidomide Mylan contains

Lenalidomide Mylan 2.5 mg hard capsules:

- The active substance is lenalidomide. Each capsule contains 2.5 mg of lenalidomide.
- The other ingredients are:
 - * capsule contents: pregelatinized maize starch, microcrystalline cellulose, sodium croscarmellose, colloidal anhydrous silica, sodium stearyl fumarate
 - * capsule shell: gelatine, titanium dioxide (E171), yellow iron oxide (E172) and indigo carmine (E132)
 - * printing ink: shellac, propylene glycol (E1520), potassium hydroxide and black iron oxide (E172).

Lenalidomide Mylan 5 mg hard capsules:

- The active substance is lenalidomide. Each capsule contains 5 mg of lenalidomide.
- The other ingredients are:
 - * capsule contents: pregelatinized maize starch, microcrystalline cellulose, sodium croscarmellose, colloidal anhydrous silica, sodium stearyl fumarate
 - * capsule shell: titanium dioxide (E171), gelatin
 - * printing ink: shellac, propylene glycol (E1520), potassium hydroxide and black iron oxide (E172).

Lenalidomide Mylan 7.5 mg hard capsules:

- The active substance is lenalidomide. Each capsule contains 7.5 mg of lenalidomide.
- The other ingredients are:
 - * capsule contents: pregelatinized maize starch, microcrystalline cellulose, sodium croscarmellose, colloidal anhydrous silica, sodium stearyl fumarate
 - * capsule shell: yellow iron oxide (E172), titanium dioxide (E171), gelatin,
 - * printing ink: shellac, propylene glycol (E1520), black iron oxide (E172) and potassium hydroxide

Lenalidomide Mylan 10 mg hard capsules:

- The active substance is lenalidomide. Each capsule contains 10 mg of lenalidomide.
- The other ingredients are:
 - * capsule contents: pregelatinized maize starch, microcrystalline cellulose, sodium croscarmellose, colloidal anhydrous silica, sodium stearyl fumarate
 - * capsule shell: gelatine, titanium dioxide (E171), black iron oxide and yellow iron oxide (E172), indigo carmine (E132)
 - * printing ink: shellac, propylene glycol (E1520), black iron oxide (E172) and potassium hydroxide

Lenalidomide Mylan 15 mg hard capsules:

- The active substance is lenalidomide. Each capsule contains 15 mg of lenalidomide.
- The other ingredients are:
 - * capsule contents: pregelatinized maize starch, microcrystalline cellulose, sodium croscarmellose, colloidal anhydrous silica, sodium stearyl fumarate
 - * capsule shell: titanium dioxide (E171), gelatin
 - * printing ink: shellac, propylene glycol (E1520), red iron oxide (E172) and simeticone

Lenalidomide Mylan 20 mg hard capsules:

- The active substance is lenalidomide. Each capsule contains 20 mg of lenalidomide.
- The other ingredients are:
 - * capsule contents: pregelatinized maize starch, microcrystalline cellulose, sodium croscarmellose, colloidal anhydrous silica, sodium stearyl fumarate
 - * capsule shell: yellow iron oxide (E172), titanium dioxide, indigo carmine (E132), gelatin
 - * printing ink: shellac, propylene glycol (E1520), red iron oxide (E172) and simeticone

Lenalidomide Mylan 25 mg hard capsules:

- The active substance is lenalidomide. Each capsule contains 25 mg of lenalidomide.
- The other ingredients are:
 - * capsule contents: pregelatinized maize starch, microcrystalline cellulose, sodium croscarmellose, colloidal anhydrous silica, sodium stearyl fumarate
 - * capsule shell: titanium dioxide (E171), gelatin
 - * printing ink: shellac, propylene glycol (E1520), potassium hydroxide, and black iron oxide (E172).

What Lenalidomide Mylan looks like and contents of the pack

Lenalidomide Mylan 2.5 mg hard capsules are green and white capsules, size 4, 14 mm, marked "MYLAN/LL 2.5".

Lenalidomide Mylan 5 mg hard capsules are white capsules, size 2, 18 mm, marked "MYLAN/LL 5".

Lenalidomide Mylan 7.5 mg hard capsules are light grey and white capsules, size 2, 18 mm, marked "MYLAN/LL 7.5".

Lenalidomide Mylan 10 mg hard capsules are green and light grey capsules, size 0, 22 mm, marked "MYLAN/LL 10".

Lenalidomide Mylan 15 mg hard capsules are white capsules, size 0, 22 mm, marked "MYLAN/LL 15".

Lenalidomide Mylan 20 mg hard capsules are green and white capsules, size 0, 22 mm, marked "MYLAN/LL 20".

Lenalidomide Mylan 25 mg hard capsules are white capsules, size 0, 22 mm, marked "MYLAN/LL 25".

Lenalidomide Mylan 2.5 mg, 7.5 mg, 20 mg and 25 mg hard capsules are provided in blister packs containing 7 hard capsules.

Lenalidomide Mylan 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg hard capsules are provided in blister packs containing 21 hard capsules and in perforated blister packs containing 21 x 1 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan,
Potters Bar,
EN6 1TL,
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This leaflet was last revised in 08/2024



ART-31346-04
75105362

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Mylan				Date of Final	dd / mm / yy	Date of Issue	dd / mm / yy	Page Count	2 of 2
Date/Time of Creation	27/07/2024 11:11	TrackWise / GLAMS ID	ART-31346-04	Client Market	United Kingdom	Software / Ver. No.	Adobe InDesign 2024		
Vendor Job No.	NA	Affiliate New Code	ART-31346-04	Product Description	LIT(BFB)LENALIDOMIDE CAPSULE(COM)PLGB V3				
Artwork Proof No.	1	Aff. Superseded Code	ART-31346-03	Pharma Code	NA	New Material Code	75105362	Actual A/w Size	Fiat - 400 x 400 mm
Product Render ID No.	NA	Barcode Information	NA	ITF Barcode	Other Sizes (if any) Folded - 40 x 70 mm				
Main Font Type - 1	Myriad Pro	SAP or SPC Code	40027141, 40027138, 40027139, 40027140, 40027141, 40027142, 40027143, 40027144, 40027145, 40027146, 40027147, 40027148, 40027149, 40027150, 40027151, 40027152, 40027153, 40027154, 40027155, 40027156, 40027157, 40027158, 40027159, 40027160, 40027161, 40027162, 40027163, 40027164, 40027165, 40027166, 40027167, 40027168, 40027169, 40027170, 40027171, 40027172, 40027173, 40027174, 40027175, 40027176, 40027177, 40027178, 40027179, 40027180, 40027181, 40027182, 40027183, 40027184, 40027185, 40027186, 40027187, 40027188, 40027189, 40027190, 40027191, 40027192, 40027193, 40027194, 40027195, 40027196, 40027197, 40027198, 40027199, 40027200, 40027201, 40027202, 40027203, 40027204, 40027205, 40027206, 40027207, 40027208, 40027209, 40027210, 40027211, 40027212, 40027213, 40027214, 40027215, 40027216, 40027217, 40027218, 40027219, 40027220, 40027221, 40027222, 40027223, 40027224, 40027225, 40027226, 40027227, 40027228, 40027229, 40027230, 40027231, 40027232, 40027233, 40027234, 40027235, 40027236, 40027237, 40027238, 40027239, 40027240, 40027241, 40027242, 40027243, 40027244, 40027245, 40027246, 40027247, 40027248, 40027249, 40027250, 40027251, 40027252, 40027253, 40027254, 40027255, 40027256, 40027257, 40027258, 40027259, 40027260, 40027261, 40027262, 40027263, 40027264, 40027265, 40027266, 40027267, 40027268, 40027269, 40027270, 40027271, 40027272, 40027273, 40027274, 40027275, 40027276, 40027277, 40027278, 40027279, 40027280, 40027281, 40027282, 40027283, 40027284, 40027285, 40027286, 40027287, 40027288, 40027289, 40027290, 40027291, 40027292, 40027293, 40027294, 40027295, 40027296, 40027297, 40027298, 40027299, 40027300, 40027301, 40027302, 40027303, 40027304, 40027305, 40027306, 40027307, 40027308, 40027309, 40027310, 40027311, 40027312, 40027313, 40027314, 40027315, 40027316, 40027317, 40027318, 40027319, 40027320, 40027321, 40027322, 40027323, 40027324, 40027325, 40027326, 40027327, 40027328, 40027329, 40027330, 40027331, 40027332, 40027333, 40027334, 40027335, 40027336, 40027337, 40027338, 40027339, 40027340, 40027341, 40027342, 40027343, 40027344, 40027345, 40027346, 40027347, 40027348, 40027349, 40027350, 40027351, 40027352, 40027353, 40027354, 40027355, 40027356, 40027357, 40027358, 40027359, 40027360, 40027361, 40027362, 40027363, 40027364, 40027365, 40027366, 40027367, 40027368, 40027369, 40027370, 40027371, 40027372, 40027373, 40027374, 40027375, 40027376, 40027377, 40027378, 40027379, 40027380, 40027381, 40027382, 40027383, 40027384, 40027385, 40027386, 40027387, 40027388, 40027389, 40027390, 40027391, 40027392, 40027393, 40027394, 40027395, 40027396, 40027397, 40027398, 40027399, 40027400, 40027401, 40027402, 40027403, 40027404, 40027405, 40027406, 40027407, 40027408, 40027409, 40027410, 40027411, 40027412, 40027413, 40027414, 40027415, 40027416, 40027417, 40027418, 40027419, 40027420, 40027421, 40027422, 40027423, 40027424, 40027425, 40027426, 40027427, 40027428, 40027429, 40027430, 40027431, 40027432, 40027433, 40027434, 40027435, 40027436, 40027437, 40027438, 40027439, 40027440, 40027441, 40027442, 40027443, 40027444, 40027445, 40027446, 40027447, 40027448, 40027449, 40027450, 40027451, 40027452, 40027453, 40027454, 40027455, 40027456, 40027457, 40027458, 40027459, 40027460, 40027461, 40027462, 40027463, 40027464, 40027465, 40027466, 40027467, 40027468, 40027469, 40027470, 40027471, 40027472, 40027473, 40027474, 40027475, 40027476, 40027477, 40027478, 40027479, 40027480, 40027481, 40027482, 40027483, 40027484, 40027485, 40027486, 40027487, 40027488, 40027489, 40027490, 40027491, 40027492, 40027493, 40027494, 40027495, 40027496, 40027497, 40027498, 40027499, 40027500, 40027501, 40027502, 40027503, 40027504, 40027505, 40027506, 40027507, 40027508, 40027509, 40027510, 40027511, 40027512, 40027513, 40027514, 40027515, 40027516, 40027517, 40027518, 40027519, 40027520, 40027521, 40027522, 40027523, 40027524, 40027525, 40027526, 40027527, 40027528, 40027529, 40027530, 40027531, 40027532, 40027533, 40027534, 40027535, 40027536, 40027537, 40027538, 40027539, 40027540, 40027541, 40027542, 40027543, 40027544, 40027545, 40027546, 40027547, 40027548, 40027549, 40027550, 40027551, 40027552, 40027553, 40027554, 40027555, 40027556, 40027557, 40027558, 40027559, 40027560, 40027561, 40027562, 40027563, 40027564, 40027565, 40027566, 40027567, 40027568, 40027569, 40027570, 40027571, 40027572, 40027573, 40027574, 40027575, 40027576, 40027577, 40027578, 40027579, 40027580, 40027581, 40027582, 40027583, 40027584, 40027585, 40027586, 40027587, 40027588, 40027589, 40027590, 40027591, 40027592, 40027593, 40027594, 40027595, 40027596, 40027597, 40027598, 40027599, 40027600, 40027601, 40027602, 40027603, 40027604, 40027605, 40027606, 40027607, 40027608, 40027609, 40027610, 40027611, 40027612, 40027613, 40027614, 40027615, 40027616, 40027617, 40027618, 40027619, 40027620, 40027621, 400						