

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986**

This medicine is dispensed with a doctor's prescription only

**Lenalidomide Taro 2.5 mg**  
**Lenalidomide Taro 7.5 mg**  
**Lenalidomide Taro 15 mg**  
**Lenalidomide Taro 25 mg**

**Lenalidomide Taro 5 mg**  
**Lenalidomide Taro 10 mg**  
**Lenalidomide Taro 20 mg**

**Capsules****Active ingredient:**

Each capsule of Lenalidomide Taro 2.5 mg contains 2.5 mg of lenalidomide

Each capsule of Lenalidomide Taro 5 mg contains 5 mg of lenalidomide

Each capsule of Lenalidomide Taro 7.5 mg contains 7.5 mg of lenalidomide

Each capsule of Lenalidomide Taro 10 mg contains 10 mg of lenalidomide

Each capsule of Lenalidomide Taro 15 mg contains 15 mg of lenalidomide

Each capsule of Lenalidomide Taro 20 mg contains 20 mg of lenalidomide

Each capsule of Lenalidomide Taro 25 mg contains 25 mg of lenalidomide

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

In addition to this leaflet, Lenalidomide Taro has a Patient Information Brochure. This brochure contains important safety information that you need to know and that you should follow before starting and during treatment with Lenalidomide Taro. The brochure focuses on the risk of birth defects to an unborn baby. Read the Patient Information Brochure and the Patient Information Leaflet before you begin taking this medicine. Keep the brochure in case you need to read it again.

**1. What is this medicine intended for?**

Lenalidomide Taro is used to treat adult patients for:

- multiple myeloma (MM)
- myelodysplastic syndromes (MDS)
- mantle cell lymphoma (MCL)
- follicular lymphoma (FL)

Lenalidomide Taro 7.5 mg is not indicated for treatment of myelodysplastic syndrome.

**Therapeutic group:** medicines that affect how your immune system works.

**How Lenalidomide Taro works**

Lenalidomide Taro works by affecting the body's immune system and directly attacking the cancer. It works in a number of different ways:

- by stopping the cancer cells developing
- by stopping blood vessels growing in the cancer
- by stimulating part of the immune system to attack the cancer cells.

## **Multiple myeloma**

Multiple myeloma is a type of cancer which affects a certain kind of white blood cell called a plasma cell. These cells collect in the bone marrow and divide, in this way growing out of control. This condition can damage the bones and kidneys.

Multiple myeloma generally cannot be cured. However, the signs and symptoms can be greatly reduced or suppressed for a period of time. This is called a 'response'.

### Newly diagnosed multiple myeloma – in patients who have had a bone marrow transplant

Lenalidomide Taro is used as a maintenance therapy after patients have recovered enough following a bone marrow transplant.

### Untreated multiple myeloma – in patients who cannot have a bone marrow transplant

Lenalidomide Taro is taken with other medicines:

- an anti-inflammatory medicine called dexamethasone
- a chemotherapy medicine called bortezomib
- a chemotherapy medicine called melphalan
- a medicine that suppresses the immune system called prednisone.

You will take these other medicines at the start of treatment and then continue to take Lenalidomide Taro on its own.

If you are aged 75 or older or have moderate to severe kidney problems, your doctor should check your condition carefully before starting treatment.

### Untreated multiple myeloma – in patients scheduled for bone marrow transplant

Multiple myeloma is cancer of the bone marrow.

Lenalidomide Taro is used to treat patients with multiple myeloma.

Lenalidomide Taro is taken with other medicines:

- an anti-inflammatory medicine called dexamethasone
- a chemotherapy medicine called bortezomib.

### Multiple myeloma – in patients who have had treatment before

Lenalidomide Taro is taken together with an anti-inflammatory medicine called dexamethasone.

Lenalidomide Taro can stop the signs and symptoms of multiple myeloma from getting worse. Lenalidomide has also been shown to delay multiple myeloma from coming back after treatment.

## **Myelodysplastic syndrome (MDS)**

MDS is a collection of many different blood and bone marrow diseases. The blood cells become abnormal and do not function properly. Patients can experience a variety of signs and symptoms including low red blood cell count (anaemia) and the need for a blood transfusion, and being at risk of infection.

Lenalidomide Taro is used to treat adult patients who have been diagnosed with MDS, when all of the following apply (Lenalidomide Taro 7.5 mg is not indicated for treatment of MDS):

- you need regular blood transfusions to treat low levels of red blood cells (transfusion-dependent anaemia)
- you have an abnormality of cells in the bone marrow called an isolated deletion 5q cytogenetic abnormality. This means your body does not make enough healthy blood cells.
- other treatments used before are unsuitable or do not work well enough.

Lenalidomide Taro can increase the number of normal red blood cells that the body produces by reducing the number of abnormal cells:

- This can reduce the number of blood transfusions needed. It is possible that you will not need treatment with blood transfusions at all.

### **Mantle cell lymphoma (MCL)**

MCL is a cancer of part of the immune system (the lymph tissue). The cancer affects a type of white blood cell called B-lymphocytes or B-cells. MCL is a disease where B-cells grow uncontrollably and collect in the lymph tissue, bone marrow, or blood.

Lenalidomide Taro is used to treat adult patients who have previously been treated with other medicines.

### **Follicular lymphoma (FL)**

FL is a slow growing cancer that affects B-cells. Patients with FL develop too many B-cells that may collect in the blood, bone marrow, lymph nodes, and spleen.

Lenalidomide Taro along with another medicine called rituximab is used to treat patients with previously treated FL.

## **2. Before using this medicine**

### **Do not use this medicine if:**

- you are sensitive (allergic) to lenalidomide or to any of the other ingredients in this medicine (see section 6, 'Additional information')
- you are pregnant, think you may be pregnant, or are planning to become pregnant. **Lenalidomide Taro is expected to be harmful to an unborn child** (see section 2, under 'Pregnancy, breast-feeding and fertility – information for men and women').
- you are of childbearing age, unless you are taking all the necessary measures to prevent pregnancy (see 'Pregnancy, breast-feeding and fertility – information for men and women').

### **Special warnings about using this medicine**

#### **Before using Lenalidomide Taro, tell your doctor if:**

- you have had blood clots in the past – you have an increased risk of developing blood clots in the veins and arteries during treatment
- you have any sign of infection such as a cough or fever
- you have or have ever had a viral infection, particularly hepatitis B viral infection, shingles, HIV. If you are in doubt, consult your doctor. Treatment with Lenalidomide Taro may cause the virus to become active again in patients who carry the virus and can lead to a recurrence of the infection. Your doctor will check whether you have ever had a hepatitis B viral infection.
- you have impaired kidney function – your doctor may need to adjust your dose of Lenalidomide Taro
- you have had a heart attack, have ever had a blood clot or if you smoke, have high blood pressure or high cholesterol levels
- you have had an allergic reaction while taking thalidomide (another medicine used to treat multiple myeloma) such as rash, itching, swelling, dizziness, or trouble breathing
- you have had one or more of the following symptoms: widespread rash, red skin, high fever, flu-like symptoms, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes – these are signs of a severe skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms - DRESS (see section 4, 'Side effects').

If any of the above conditions applies to you, tell your doctor before starting treatment.

At any time during or after your treatment, tell your doctor immediately, if:

- you experience blurred, loss of or double vision, difficulty speaking, weakness in the arms or legs, a change in the way you walk or problems with your balance, persistent

numbness, decreased sensation or loss of sensation, memory loss or confusion. These may all be symptoms of a serious and potentially fatal brain condition called progressive multifocal leukoencephalopathy (PML). If you experienced these symptoms before treatment with Lenalidomide Taro, tell your doctor about any change in these symptoms.

- you experience shortness of breath, tiredness, dizziness, chest pain, fast heartbeat, or swelling in the legs or ankles. These may be symptoms of a serious condition called pulmonary hypertension (see section 4, 'Side effects').

### **Children and adolescents**

Lenalidomide Taro is not recommended for use in children and adolescents under 18 years.

### **Tests and follow-up**

Before and during the treatment with Lenalidomide Taro, you will have to have regular blood tests, because the medicine may cause a fall in the number of blood cells that help fight infection (white blood cells) and help the blood clotting process (platelets).

Your doctor will ask you to have periodic blood tests:

- before treatment
- every week for the first 8 weeks of treatment
- then at least every month after that.

You may be evaluated for signs of heart-lung problems before and during your treatment with Lenalidomide Taro.

#### Patients with MDS taking Lenalidomide Taro

- If you have MDS, you are more likely to get a more advanced condition called acute myeloid leukaemia (AML). In addition, it is not known how lenalidomide affects the chances of you getting AML. Your doctor may do tests to check for signs which may better predict the likelihood of you getting AML during your treatment with Lenalidomide Taro.

#### For patients with MCL taking Lenalidomide Taro

Your doctor will ask you to have blood tests:

- before treatment
- every week for the first 8 weeks (2 cycles) of treatment
- then every 2 weeks during cycles 3 and 4 (see section 3 under 'Treatment cycles' for more information)
- after this, at the start of each treatment cycle
- and at least every month.

#### For patients with FL taking Lenalidomide Taro

Your doctor will ask you to have blood tests:

- before treatment
- every week for the first 3 weeks (first cycle) of treatment
- every 2 weeks during cycles 2 to 4 (see section 3 under 'Treatment cycles' for more information)
- after this, at the start of each treatment cycle
- and at least every month.

Your doctor may check if you have a high total amount of tumours throughout your body, including your bone marrow. This could lead to a condition where the tumours break down and cause unusual levels of chemicals in the blood, which can lead to kidney failure (this condition is called tumour lysis syndrome).

Your doctor may check you for changes to your skin such as red spots or rash.

Your doctor may adjust your dose of Lenalidomide Taro or stop your treatment based on the results of your blood tests and on your general condition. If you are newly diagnosed with multiple myeloma, your doctor may assess your treatment based on your age and other conditions you already have.

For tests and follow-up related to use during childbearing age (for men and women), please see the information in the box at the beginning of the leaflet, and the information that appears under 'Pregnancy, breast-feeding, and fertility'.

#### **Blood donation**

Do not donate blood during treatment with Lenalidomide Taro, during treatment interruptions, and for 4 weeks after the end of treatment.

#### **Sperm donation**

Do not donate sperm during treatment with Lenalidomide Taro, during treatment interruptions, and for 4 weeks after the end of treatment.

#### **The elderly and patients with impaired kidney function**

If you are aged 75 or older or have moderate to severe kidney problems, your doctor will check your condition carefully before starting treatment.

#### **Interactions with other medicines**

**If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- some medicines used to prevent pregnancy such as birth control pills, because they may not work
- some medicines used to treat heart problems – such as digoxin – periodic monitoring (follow-up) of digoxin levels in the blood during treatment with Lenalidomide Taro is recommended
- some medicines used to thin the blood – such as warfarin – close monitoring (follow-up) of warfarin levels in the blood is recommended during combined treatment with dexamethasone
- medicines in the erythropoietin group (for treatment of anaemia) or other medicines that may increase the risk of thrombosis in the blood vessels, such as hormone replacement therapy
- medicines in the statin group – there is an increased risk of rhabdomyolysis when statins are taken with lenalidomide. Periodic monitoring (follow-up) is recommended, especially during the first weeks of treatment.

#### **Using this medicine and food**

This medicine can be taken with or without food.

#### **Pregnancy, breast-feeding, and fertility – information for men and women**

##### **Pregnancy**

Your doctor will enrol you in the Risk Management Program/Pregnancy Prevention Program (RMP/PPP).

This program is designed to help your doctor advise you about the risks involved in Lenalidomide Taro therapy and to ensure that you are aware of the precautions you need to take before, during, and after treatment.

##### Information for women taking Lenalidomide Taro

- You must not use Lenalidomide Taro if you are pregnant, as the medicine is expected to harm an unborn baby.
- You must not become pregnant while being treated with Lenalidomide Taro. Therefore, if you are a woman of childbearing age, you must use effective methods of contraception (see 'Contraception').
- If you do become pregnant during your treatment with Lenalidomide Taro, you must stop the treatment and inform your doctor immediately.
- Wait 4 more weeks after you stop using the medicine before trying to become pregnant.

Information for men taking Lenalidomide Taro

- If your partner becomes pregnant while you are taking Lenalidomide Taro, you must inform your doctor immediately. It is recommended that your partner seek medical advice as soon as possible.
- You must use effective methods of contraception (see 'Contraception').

**Breast-feeding**

You must not breast-feed during treatment with Lenalidomide Taro and during treatment interruptions, as it is not known if lenalidomide passes into breast milk.

**Contraception**Information for women taking Lenalidomide Taro

Before starting treatment with this medicine, ask your doctor about your ability to become pregnant, even if you think that the chances of your becoming pregnant are low.

If you are able to become pregnant:

- You must have pregnancy tests under the supervision of your doctor (before every treatment, at least every 4 weeks during treatment, during treatment interruptions, and for at least 4 weeks after the end of treatment) except if you have undergone a procedure that prevents eggs from passing through the fallopian tubes to the uterus (tubal sterilisation).

**And –**

- You must use 2 effective methods of contraception at the same time each time, for at least 4 weeks before starting treatment, during treatment, during treatment interruptions and for at least 4 weeks after the end of treatment – unless refraining from sexual activity with a man is your chosen method.

Your doctor will advise you on appropriate methods of contraception.

Information for men taking Lenalidomide Taro

Lenalidomide passes into semen. If your female partner is pregnant or able to become pregnant, and is not using effective methods of contraception, you must use condoms during your treatment and for at least 4 weeks after the end of treatment, even if you have had sterilisation surgery (vasectomy).

If you cannot use condoms, make sure that your female partner is using at least one form of effective contraception for 4 weeks before starting treatment, during treatment, during treatment interruptions, and for 4 weeks after the end of treatment.

Do not donate sperm during treatment with Lenalidomide Taro, during treatment interruptions, and for 4 weeks after the end of treatment.

**Driving and using machines**

Do not drive or operate machines if you feel dizzy, tired, sleepy, or have vertigo or blurred vision.

**Important information about some of this medicine's ingredients**

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before starting treatment with this medicine.

This medicine contains less than 23 mg sodium per capsule and is therefore considered sodium-free.

**3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

**Only your doctor will determine your dose and how you should take this medicine.**

- When Lenalidomide Taro is used to treat multiple myeloma in patients who cannot have a bone marrow transplant, patients who are scheduled for a bone marrow transplant, or

patients who have had other treatments before, it is given with other medicines (see section 1, 'What is this medicine intended for?').

- When Lenalidomide Taro is used to treat multiple myeloma in patients who have had a bone marrow transplant or to treat patients with MDS or MCL, it is given alone.
- When Lenalidomide Taro is used to treat follicular lymphoma, it is given with another medicine that contains an active ingredient called rituximab.

**If you are taking Lenalidomide Taro in combination with other medicines, you should read the leaflets that come with these medicines for further information on their use and effects.**

**Do not exceed the recommended dose.**

Use this medicine at set intervals, as determined by your doctor. It is important that you do not skip any doses.

Treatment cycles:

This medicine is taken on certain days over 3 weeks (21 days).

- Every 21 days is called a treatment cycle.
- Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you will not take any medicine.
- After completing each 21-day cycle, you should start a new cycle over the next 21 days.

OR

- This medicine is taken on certain days over 4 weeks (28 days).
- Every 28 days is called a treatment cycle.
- Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you will not take any medicine.
- After completing each 28-day cycle, you should start a new cycle over the next 28 days.

How much Lenalidomide Taro to take:

Before you start treatment, your doctor will tell you:

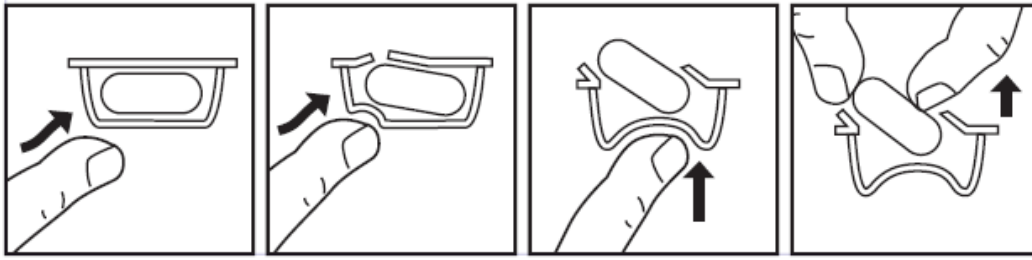
- how much Lenalidomide Taro you should take
- how much of the other medicines you should take in combination with Lenalidomide Taro, if any
- on what days of your treatment cycle to take each medicine.

Method of administration:

- Swallow the capsules whole (preferably with water).
- Do not break, open, or chew the capsules. If powder from a broken Lenalidomide Taro capsule makes contact with your skin, wash the skin thoroughly and immediately with soap and water.
- Healthcare professionals, caregivers, and family members should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.
- The capsules can be taken either with or without food.
- You should take the medicine at about the same time on the scheduled days.

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 treatment:

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

**Crushing/splitting/chewing**

**Do not open, chew, or break the capsule.**

If powder from a broken capsule makes contact with the skin, wash the skin thoroughly with soap and water immediately.

**If you have accidentally taken a higher dose**

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

**If you forget to take the medicine**

If you forget to take this medicine at the scheduled time

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

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

**Do not take medicines in the dark! Check the label and dose every time you take this medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

**4. Side effects:**

As with any medicine, using Lenalidomide Taro may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

**Stop taking Lenalidomide Taro and consult your doctor immediately if you notice any of the following serious side effects – you may need urgent medical treatment:**

- hives, rash, swelling of eyes, mouth or face, difficulty breathing, or itching, which may be symptoms of serious 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 problems (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 section 2 under 'Special warnings about using this medicine').

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

- fever, chills, sore throat, cough, mouth ulcers or any other symptom of infection, including an infection in 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 a high level of calcium in the blood.

Lenalidomide Taro may reduce the number of white blood cells that fight infection and also the number of blood cells which help the blood to clot (platelets), which may lead to bleeding disorders such as nosebleeds and bruising. Lenalidomide Taro may also cause blood clots in the veins (thrombosis).

**Additional side effects**

It is important to note that a small number of patients may develop additional types of cancer, and that this risk may be increased with use of Lenalidomide Taro. Therefore, your doctor will carefully monitor your condition regarding new types of cancer while you are being treated with Lenalidomide Taro.

**Very common side effects – affect more than 1 in 10 users:**

- a fall in the number of red blood cells, which may lead to anaemia causing tiredness and weakness
- rash, itching
- muscle cramps, muscle weakness, muscle pain, 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 pain, headache, earache, cough, and chills
- numbness, tingling or burning sensation on the skin, pain 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 symptoms of blood clots in the lungs, a condition called pulmonary embolism)
- infections of all types, including infection of the sinuses that surround the nose, infection of the lungs and the upper respiratory tract
- shortness of breath
- blurred vision
- clouding of the 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 protein values in the blood that can cause swelling of the arteries (vasculitis)
- increase in blood sugar level (diabetes)
- decrease in blood sugar level
- headaches
- nosebleed
- dry skin
- depression, mood changes, difficulty sleeping

- cough
- a fall in blood pressure
- a feeling of bodily discomfort, feeling bad
- sore and inflamed mouth, dry mouth
- dehydration

**Common side effects – affect 1–10 in 100 users:**

- 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 heartbeat (pulse)
- 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 the body
- excessive darkening of your skin, discolouration of your skin resulting from bleeding underneath, typically caused by bruising, swelling of skin filled with blood, bruises
- increase in uric acid in the blood
- skin eruptions, redness of skin, cracking skin, peeling skin, hives
- increased sweating, night sweats
- difficulty swallowing, sore throat, difficulty with voice quality or voice changes
- runny nose
- production of more or less urine than usual or an 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 inner ear which leads to feeling that everything is spinning), temporary loss of consciousness
- chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, nausea 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 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 – affect 1–10 in 1,000 users:**

- 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)
- yellowing of the skin, mucus membranes or eyes (jaundice), pale coloured stools, dark coloured urine, itchy skin, rash, pain or swelling of the stomach – these may be symptoms of liver injury (hepatic failure)

- stomach pain, bloating, or diarrhoea, which may be symptoms of inflammation in the large intestine (called colitis or caecitis)
- damage to kidney cells (renal tubular necrosis)
- changes in 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 breakdown products of dying cancer cells and may include changes to blood chemistry, high potassium, phosphorus, and uric acid, and low calcium consequently leading to changes in kidney function, heart rate (pulse), seizures, and sometimes death.
- increase in blood pressure in the blood vessels that supply blood to the lungs (pulmonary hypertension).

**Side effects with unknown frequency (effects whose frequency has not yet been established yet):**

- 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 indicate 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 cause kidney problems (rhabdomyolysis) have been observed, some of them when lenalidomide was taken with a statin (a type of cholesterol lowering medicine)
- 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 serious infections. Contact your doctor if you have severe stomach pain, fever, nausea, vomiting, blood in your stool, or changes in bowel habits (bowel movements).
- viral infections, including herpes zoster (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, nausea or vomiting).
- rejection of a transplanted organ (such as kidney, heart).

**If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

**Reporting side effects:**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

**5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

**Storage conditions:**

Store below 25°C.

Return all unused capsules to the pharmacy.

**6. Additional information**

**In addition to the active ingredient, this medicine also contains:**

Capsule content:

lactose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

**Capsule body:**

gelatine, titanium dioxide, yellow iron oxide (Lenalidomide Taro 2.5 mg, 7.5 mg, 10 mg and 20 mg), indigotine (indigo carmine) (Lenalidomide Taro 2.5 mg, 10 mg, 15 mg and 20 mg).

**Printing ink:**

iron oxide black, shellac, propylene glycol, potassium hydroxide.

**What the medicine looks like and contents of the pack:**

Lenalidomide Taro 2.5 mg: opaque capsule with a white body and green cap. 'L9NL' and '2.5' printed on the capsule body.

Lenalidomide Taro 5 mg: opaque, white capsule. 'L9NL' and '5' printed on the capsule body.

Lenalidomide Taro 7.5 mg: opaque capsule with a white body and yellow cap. 'L9NL' and '7.5' printed on the capsule body.

Lenalidomide Taro 10 mg: opaque capsule with a yellow body and green cap. 'L9NL' and '10' printed on the capsule body.

Lenalidomide Taro 15 mg: opaque capsule with a white body and blue cap. 'L9NL' and '15' printed on the capsule body.

Lenalidomide Taro 20 mg: opaque capsule with a blue body and green cap. 'L9NL' and '20' printed on the capsule body.

Lenalidomide Taro 25 mg: opaque white capsule. 'L9NL' and '25' printed on the capsule body.

Lenalidomide Taro packs contain 7, 14, 21, 28, or 42 capsules packaged in blister trays.

Not all pack sizes may be marketed.

**Registration holder's name and address:**

Taro International Ltd.,  
14 HaKitor St., Haifa Bay 2624761.

**Manufacturer's name and address:**

Synthon Hispania S.L., Spain  
C/Castello, 1, 08830 Sant Boi De Llobregat, Barcelona, Spain.

Revised in November 2024.

Registration numbers of the medicine in the Ministry of Health's National Drug Registry:

Lenalidomide Taro 2.5 mg:	174-53-36509-99
Lenalidomide Taro 5 mg:	174-54-36510-99
Lenalidomide Taro 7.5 mg:	174-55-36511-99
Lenalidomide Taro 10 mg:	174-56-36512-99
Lenalidomide Taro 15 mg:	174-57-36513-99
Lenalidomide Taro 20 mg:	174-58-36514-99
Lenalidomide Taro 25 mg:	174-59-36515-99

For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:



Lenalidomide Taro  
2.5 mg



Lenalidomide Taro  
5 mg



Lenalidomide Taro  
7.5 mg



Lenalidomide Taro  
10 mg



Lenalidomide Taro  
15 mg



Lenalidomide Taro  
20 mg



Lenalidomide Taro  
25 mg

<https://israeldrugs.health.gov.il/#!/medDetails/174%2053%2036509%2099>

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For a printed copy of the patient information leaflet in English, please contact the registration holder by email [Info@taro.com](mailto:Info@taro.com) or by phone 1-800-464-664.