Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986
This medicine is dispensed with a doctor's prescription only

Revlimid 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg
Hard capsules

Each hard capsule contains:
Lenalidomide 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg or 25 mg.

Inactive ingredients and allergens: see section **'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 the leaflet, Revlimid has a Patient Information Brochure. This brochure contains important safety information that you need to know, before starting and during treatment with Revlimid and you should act according to it. 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 the medicine. Keep the brochure for future reference if necessary.

1. What is this medicine intended for?

Revlimid is used in adult patients for:
- Multiple myeloma
- Myelodysplastic syndromes (MDS)
- Mantle cell lymphoma (MCL)
- Follicular lymphoma

Revlimid 7.5 mg is not indicated for treatment of myelodysplastic syndromes.

Therapeutic group: The medicine belongs to a group of medicines which affect how your immune system works.

How Revlimid works
Revlimid 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 the plasma cell. These cells collect in the bone marrow and divide, becoming out of control. This can damage the bones and kidneys.

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

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

Revlimid is used on its own 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
Revlimid is taken with other medicines:
An anti-inflammatory medicine called 'dexamethasone',
A chemotherapy medicine called 'bortezomib',
A chemotherapy medicine called 'melphalan'
An immunosuppressant medicine called 'prednisone'.
You will take these other medicines at the start of treatment and then continue to take Revlimid on its own.

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

Untreated multiple myeloma – in patients scheduled for bone marrow transplant
Multiple myeloma (*MM*) is cancer of the bone marrow.
Revlimid is used to treat patients with multiple myeloma.
Revlimid is taken with other medicines:
An anti-inflammatory medicine called 'dexamethasone',
A chemotherapy medicine called 'bortezomib'.

Multiple myeloma – in patient who have had treatment before
Revlimid is taken together with an anti-inflammatory medicine called 'dexamethasone'.

Revlimid can stop the signs and symptoms of multiple myeloma from getting worse. It has also been shown to delay multiple myeloma from coming back following treatment.

Myelodysplastic syndromes *(*MDS)
MDS are 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 a low red blood cell count (anaemia), the need for a blood transfusion, and be at risk of infection.

Revlimid is used to treat adult patients who have been diagnosed with MDS, when all of the following apply (Revlimid 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 have been used before, are not suitable or do not work well enough

Revlimid can increase the number of healthy 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 no treatment through administration of blood units will be needed.

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 in an uncontrolled way and build up in the lymph tissue, bone marrow or blood.

Revlimid 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 the B-lymphocytes. A patient with FL develops too many B-lymphocytes that may collect in the blood, bone marrow, lymph nodes and spleen.

Revlimid along with another medicine called rituximab are used to treat patients with previously treated follicular lymphoma.

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 of this leaflet: **'Additional information'**).
- You are pregnant, think you may be pregnant or are planning to become pregnant. **Revlimid is expected to be harmful to an unborn child** (please see section 2, 'Pregnancy, breast-feeding and fertility – information for men and women').
- If you are of childbearing potential - do not use this medicine without following all the necessary measures to prevent pregnancy (please see 'Pregnancy, breast-feeding and fertility – information for men and women').

Special warnings about using this medicine:

Before using Revlimid, 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 previous viral infection, particularly hepatitis B, varicella zoster, HIV. If you are in doubt, consult with your doctor. Treatment with Revlimid may cause the virus to become active again in patients who carry the virus and lead to a recurrence of the infection. Your doctor will check whether you have ever had hepatitis B infection.
- You have impaired kidney function - your doctor may need to adjust your dose of the medicine.
- 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 whilst taking thalidomide (another medicine used to treat multiple myeloma) such as rash, itching, swelling, dizziness or trouble breathing.
- You have experienced in the past one or more of the following symptoms: widespread rash, red skin, high fever, flu-like symptoms, liver enzyme elevations, blood abnormalities (increase in white blood cell levels), 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 known as progressive multifocal leukoencephalopathy (PML). If you experienced these symptoms before treatment with Revlimid, tell your doctor about any change in these symptoms.
- You experience shortness of breath, tiredness, dizziness, pain in the chest, a faster heartbeat, or swelling in the legs or ankles. These may be symptoms of a serious condition called pulmonary hypertension (see section 4).

Smoking

It is recommended that you refrain from smoking during treatment.
Smoking may increase the occurrence of blood clots and heart attacks.

Children and adolescents

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

Tests and follow-up

Before and during the treatment with Revlimid, you will 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 cardiopulmonary problems before and during the treatment with Revlimid.

Patients with MDS taking Revlimid

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

For patients with MCL taking Revlimid

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 in cycles 3 and 4 (see section 3 ‘Treatment cycles’ for more information)
- After this, at the start of each treatment cycle and
- at least every month

For patients with FL taking Revlimid

Your doctor will ask you to have blood tests:

- Before treatment
- Every week for the first 3 weeks (1 cycle) of treatment
- Every 2 weeks in cycles 2 to 4 (see section 3 '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 the 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 rashes.

Your doctor may adjust your dose of Revlimid 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 also 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 Revlimid, during treatment interruptions, and for 4 weeks after the end of treatment.

Sperm donation

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

Elderly and people with impaired kidney function
If you are aged 75 years or older or have moderate to severe kidney problems, your doctor will check your condition carefully before starting treatment.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. In particular, if you are taking:

- Medicines used to prevent pregnancy - such as birth control pills, because of the concern that they will be less effective during use of the medicine.
- Some medicines used to treat heart problems - such as digoxin - periodic monitoring (follow-up) of digoxin levels in the blood during treatment with Revlimid is recommended.
- Some medicines used to thin the blood - such as warfarin – close monitoring (follow-up) of warfarin levels in the blood 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 Revlimid. Periodic monitoring (follow-up) is recommended, especially in the first weeks of treatment.

Using this medicine and food
The 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 Revlimid therapy and to ensure that you are aware of the precautions you need to take before, during and after treatment.

<u>Information for women taking Revlimid</u>

- You must not take this medicine if you are pregnant or are planning to become pregnant, as Revlimid is expected to be harmful to an unborn baby.
- You must not become pregnant while being treated with Revlimid. Therefore, if you are of childbearing potential, do not use the medicine without using effective methods of contraception (see 'Contraception').
- If you do become pregnant during your treatment with Revlimid, 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.

<u>Information for men taking Revlimid</u>

- If your partner becomes pregnant whilst you are taking Revlimid, you should 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 Revlimid and during treatment interruptions, as it is not known if Revlimid passes into breast milk.

Contraception
<u>Information for women taking Revlimid</u>
Before starting the treatment with the medicine, ask your doctor if you are able to become pregnant, even if you think that the chances of your becoming pregnant are low.
If you are able to become pregnant:

- You will 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 treatment has finished) except if you have undergone a procedure that prevents the eggs from passing through the fallopian tubes to the uterus.

And -

- You must use two 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 stopping 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 Revlimid
Revlimid passes into semen. If your female partner is pregnant or able to become pregnant, you must use condoms during the treatment and for at least 4 weeks after the end of treatment (even if you have had a 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 stopping treatment.
Do not donate sperm during treatment with Revlimid, during treatment interruptions, and for 4 weeks after stopping treatment.

Driving and using machines

Use of this medicine may make you feel dizzy, tired, sleepy or have blurred vision and therefore requires caution when driving a vehicle, operating dangerous machines and any activity that requires you to be alert.

Important information about some of this medicine's ingredients
Revlimid contains lactose.
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before starting to take this medicine.

3. How to use this medicine?

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

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

- When Revlimid 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 the medicine intended for?').
- When Revlimid 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 Revlimid is used to treat follicular lymphoma, it is given with another medicine that contains an active ingredient called rituximab.

If you are taking Revlimid in combination with other medicines, you should refer to 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 of the medicines.
- After completing every 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).

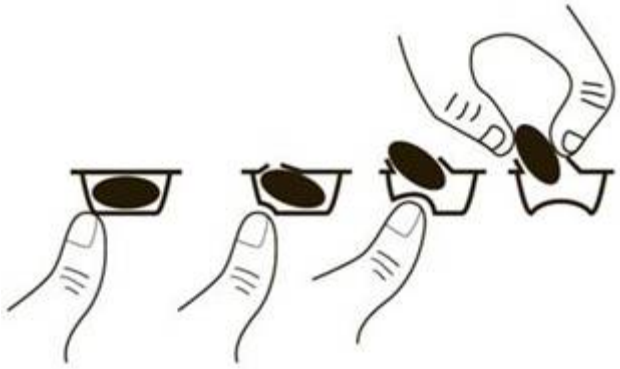
- Every 28 days is called a 'treatment cycle'.

- 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 of the medicines.
- After completing every 28-day cycle, you should start a new 'cycle' over the next 28 days.

How much Revlimid to take:
Before you start treatment, your doctor will tell you:
- How much Revlimid you should take.
- How much of the other medicines you should take in combination with Revlimid, 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 Revlimid capsule makes contact with the 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 the treatment
Revlimid is taken in treatment cycles, each cycle lasting 21 or 28 days (see above 'Treatment cycles'). You should continue the cycles of treatment until your doctor tells you to stop.

Crushing/splitting/chewing
Do not open, chew or break the hard capsule. If powder from a broken capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.

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 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.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine:
Do not stop taking the medicine without consulting your doctor.

How can you contribute to the success of the treatment?
Complete the full course of treatment as recommended by your doctor.
Even if your health improves, do not stop treatment with this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take 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:

Like with all medicines, using Revlimid 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 Revlimid and consult your 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 section 2 'Special warnings regarding the use of this medicine').

Serious side effects that may affect more than 1 in 10 patients
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 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 a high level of calcium in the blood.

Revlimid 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. Revlimid may also cause blood clots in the veins (thrombosis), arteries or lungs, which could lead to a blood clot in the lung, heart attack or stroke.

Additional serious 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 use of Revlimid. Therefore, your doctor will carefully monitor your condition regarding new types of cancer while you are being treated with Revlimid.

Very common side effects that may affect more than 1 in 10 patients:

- 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, a condition 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 the eye lens (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 change, 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 that may affect up to 1 in 10 patients:

- 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
- 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, discoloration 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, 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 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, 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 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 that may affect up to 1 in 100 patients:

- 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 changes to blood chemistry; high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heart beat (pulse), seizures, and sometimes death
- Increase in blood pressure within blood vessels that supply blood to the lungs (pulmonary hypertension)

Side effects with unknown frequency - Frequency of the side effects 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 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 lead to kidney problems (rhabdomyolysis) have been observed, some of them when Revlimid is 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 (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 nausea).
- Rejection of organ transplant (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.
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) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il
And by e-mail to the registration holder's Patient Safety Unit: drugsafety@neopharmgroup.com

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 a 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:
Do not store above 25°C.
Even if kept according to the recommended package/storage conditions, medicines keep for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
Do not store different medicines in the same package.
Return all unused Revlimid capsules to the pharmacist or doctor.

6. Additional information

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

Lactose:
Revlimid 2.5 mg - lactose anydrous 73.5 mg
Revlimid 5 mg - lactose anydrous 147 mg
Revlimid 7.5 mg - lactose anydrous 144.5 mg
Revlimid 10 mg - lactose anydrous 294 mg
Revlimid 15 mg - lactose anydrous 289 mg
Revlimid 20 mg - lactose anydrous 244.5 mg
Revlimid 25 mg - lactose anydrous 200 mg

Inactive ingredients:
Lactose anhydrous, microcrystalline cellulose, croscarmellose sodium, magnesium stearate

Capsule shell:
Revlimid 2.5 mg: gelatin, titanium dioxide, FD&C Blue no.2 and yellow iron oxide (FDA/E172)
Revlimid 5 mg: gelatin and titanium dioxide
Revlimid 7.5 mg: gelatin, titanium dioxide and yellow iron oxide (FDA/E172)
Revlimid 10 mg: gelatin, titanium dioxide, FD&C Blue no.2 and yellow iron oxide (FDA/E172)
Revlimid 15 mg: gelatin, titanium dioxide and FD&C Blue no.2
Revlimid 20 mg: gelatin, titanium dioxide, FD&C Blue no.2 and yellow iron oxide (FDA/E172)
Revlimid 25 mg: gelatin and titanium dioxide

Printing ink: shellac, dehydrate alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, purified water, strong ammonia solution, potassium hydroxide and black iron oxide.

What the medicine looks like and the contents of the pack:
- Revlimid 2.5 mg: Blue-green/white hard capsules, with 'REV 2.5 mg' written on them.

- Revlimid 5 mg: White hard capsules, with ‘REV 5 mg’ written on them.
- Revlimid 7.5 mg: Pale yellow/white hard capsules, with ‘REV 7.5 mg’ written on them.
- Revlimid 10 mg: Blue-green/pale yellow hard capsules, with ‘REV 10 mg’ written on them.
- Revlimid 15 mg: Pale blue/white hard capsules, with ‘REV 15 mg’ written on them.
- Revlimid 20 mg: Blue-green/pale blue hard capsules, with ‘REV 20 mg’ written on them.
- Revlimid 25 mg: White hard capsules, with ‘REV 25 mg’ written on them.

The capsules come in packs. Each pack contains three blisters, each blister with seven capsules. This gives a total of 21 capsules per pack.

Registration holder and address:
Neopharm Scientific Ltd., 6 Hashiloach St., POB 7063, Petach Tikva 4917001.

Manufacturer’s name and address:
Celgene International Sarl, Boudry, Switzerland.

Revised in August 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Revlimid 2.5 mg: 151-24-33894
Revlimid 5 mg: 140-45-31660
Revlimid 7.5 mg: 151-25-33896
Revlimid 10 mg: 140-46-31661
Revlimid 15 mg: 140-47-31662
Revlimid 20 mg: 151-26-33965
Revlimid 25 mg: 140-48-31663