Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Revlimid is and what it is used for
2. What you need to know before you take Revlimid
3. How to take Revlimid
4. Possible side effects
5. How to store Revlimid
6. Content of the pack and other information

1. What Revlimid is and what it is used for

What Revlimid is
Revlimid contains the active substance ‘lenalidomide’. This medicine belongs to a group of medicines which affect how your immune system works.

What Revlimid is used for

Multiple myeloma
- Revlimid is used with another medicine called ‘dexamethasone’ (an anti-inflammatory medicine) to treat adults with a type of cancer called multiple myeloma. It is used when you have already had one or more other types of treatment before.

Myelodysplastic syndromes
Revlimid is also used alone to treat adult patients who have been diagnosed with myelodysplastic syndromes, when all of the following apply:
- 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 cytogenic abnormality’. This means you do not make enough healthy blood cells
- other treatments have been used before, are not suitable or do not work well enough.

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

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

**What are myelodysplastic syndromes**
Myelodysplastic syndromes (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 a risk of infection.

**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**
Revlimid can stop the signs and symptoms of multiple myeloma getting worse:
- Revlimid delayed the recurrence of multiple myeloma for up to 48 weeks compared to 20 weeks for those who were not taking Revlimid.

**Myelodysplastic syndromes**
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 transfusions will be needed.

### 2. What you need to know before you take Revlimid

**Do not take Revlimid:**

- if you are pregnant or think you may be pregnant or are planning to become pregnant, **as Revlimid is expected to be harmful to an unborn child** (see section 2, “Warnings and precautions” and “Pregnancy and breast-feeding”).
- if you are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see section 2, “Warnings and precautions” and “Pregnancy and breast-feeding”). If you are able to become pregnant, your doctor will record with each prescription that the necessary measures have been taken and will provide you with this confirmation.
- if you are allergic to lenalidomide or any of the other ingredients of this medicine listed in section 6. If you think you may be allergic, ask your doctor for advice.

If any of these apply to you, tell your doctor before you take Revlimid.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Revlimid.
For women taking Revlimid
Before starting the treatment, you should ask your doctor if you are able to become pregnant, even if you think this is unlikely.

If you are able to become pregnant
• you will have pregnancy tests under the supervision of your doctor (before every treatment, every 4 weeks during treatment, and 4 weeks after the treatment has finished) except where it has been confirmed that the fallopian tubes have been severed and sealed, to stop eggs from reaching the uterus (tubal sterilisation)

AND
• you must use effective methods of contraception for 4 weeks before starting treatment, during treatment, and until 4 weeks after stopping treatment. Your doctor will advise you on appropriate methods of contraception.

For men taking Revlimid
Revlimid passes into human semen. If your female partner is pregnant or able to become pregnant, and she does not use effective methods of contraception, you must use condoms during treatment and 1 week after the end of treatment, even if you have had a vasectomy.

All patients
Before starting the treatment you should tell your doctor if you had blood clots in the past.
During the treatment with Revlimid you have an increased risk of developing blood clots in the veins and arteries.

Before and during the treatment with Revlimid you will have regular blood tests as Revlimid may cause a fall in the blood cells that help fight infection (white blood cells) and help the blood to clot (platelets).

Your doctor should ask you to have a blood test:
• before treatment
• every week for the first 8 weeks of treatment
• at least every month after that.

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.

Before you start treatment you should tell your doctor if you have kidney disease. Your doctor may adjust your dose of Revlimid based on this information.

You should not donate blood during treatment and for 1 week after the end of treatment.

Please tell your doctor if you have:
• had a heart attack, have ever had a blood clot, or if you smoke, have high blood pressure or high cholesterol levels.
• a high total amount of tumour 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).
• had an allergic reaction whilst taking thalidomide such as rash, itching, swelling, dizziness or trouble breathing.

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

At the end of the treatment you should return all unused capsules to the pharmacist.

**Children and adolescents**
Revlimid is not recommended for use in children and young people under 18 years.

**Other medicines and Revlimid**
Tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription including herbal medicines. This is because Revlimid can affect the way some other medicines work. Also, some other medicines can affect the way Revlimid works.

In particular, tell your doctor or nurse if you are taking any of the following medicines:
- some medicines used to prevent pregnancy such as oral contraceptives, as they may stop working
- some medicines used for heart problems – such as digoxin
- some medicines used to thin the blood – such as warfarin

**Pregnancy and breast-feeding**

**Pregnancy**

For women taking Revlimid
You must not take Revlimid if you are pregnant, as it is expected to be harmful for an unborn baby. In addition, you must not become pregnant while taking Revlimid. Therefore you must use effective methods of contraception if you are a woman of childbearing potential (see section 2, “What you need to know before you take Revlimid”).

If you do become pregnant during the treatment with Revlimid, you must stop the treatment and inform your doctor immediately.

For men taking Revlimid
For men taking Revlimid, please see section 2, “What you need to know before you take Revlimid”. If your partner becomes pregnant whilst you are taking Revlimid, you should inform your doctor immediately. It is recommended that your partner seeks medical advice.

**Breast-feeding**
You should not breast-feed when taking Revlimid, as it is not known if Revlimid passes into human milk.

**Driving and using machines**
Do not drive or operate machines if you experience side effects such as dizziness, tiredness, sleepiness or blurred vision.

**Revlimid contains lactose**
Revlimid contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Revlimid.
3. **How to take Revlimid**

Revlimid must be given to you by healthcare professionals with experience in treating multiple myeloma or myelodysplastic syndromes.

When used to treat multiple myeloma, Revlimid is taken in combination with dexamethasone. When used to treat myelodysplastic syndromes, it is taken alone. Always take Revlimid alone or Revlimid and dexamethasone in combination exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. You should refer to the package leaflet of dexamethasone for further information on its use and effects.

**Multiple myeloma**

**Revlimid dose**

The recommended dose is 25 mg once per day. Revlimid is taken in treatment cycles, each cycle lasting 28 days.

**Treatment cycle:**
- On days 1-21: take 25 mg of Revlimid once per day
- On days 22-28: do **NOT** take Revlimid

After completing each cycle, start a new one.

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 (see section 2, “What you need to know before you take Revlimid”).

**Dexamethasone dose**

The usual starting dose is 40 mg once per day. Dexamethasone is also taken in treatment cycles, each cycle lasting 28 days.

**First 4 treatment cycles:**
- On days 1-4, 9-12 and 17-20: take 40 mg dexamethasone once per day
- On days 21-28: do **NOT** take dexamethasone

**Following treatment cycles:**
- On days 1-4: take 40 mg dexamethasone once per day
- On days 5-28: do **NOT** take dexamethasone

After completing each cycle, start a new one.

Your doctor may reduce your dose of dexamethasone based on your general condition.

**Myelodysplastic syndromes**

**Revlimid dose**

The usual starting dose is 10 mg once per day. Revlimid is taken in treatment cycles, each cycle lasting 28 days.

**Treatment cycle:**
- On days 1-21: take 10 mg of Revlimid once per day
• On days 22-28: do NOT take Revlimid
  After completing each cycle, start a new one.

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 (see Section 2, “What you need to know before you take Revlimid”).

**All patients**

**How and when to take Revlimid**
You should swallow the Revlimid capsules whole, preferably with water, once a day. Do not break, open or chew the capsules. The Revlimid capsules can be taken either with or without food.

You should take Revlimid at about the same time each day.

**Duration of the treatment with Revlimid**
Revlimid is taken in treatment cycles, each cycle lasting 28 days (see above “Treatment cycle”). You should continue the cycles of treatment until your doctor tells you to stop.

**If you take more Revlimid than you should**
If you take more Revlimid than was prescribed, tell your doctor immediately.

**If you forget to take Revlimid**
If you forget to take Revlimid 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, Revlimid can cause side effects, although not everybody gets them.

**Serious side effects which may affect more than 1 in 10 people**
Revlimid 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 e.g. nosebleeds and bruising. Revlimid may also cause blood clots in the veins (thrombosis).

Therefore **you must tell your doctor immediately** if you experience:
• fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection
• bleeding or bruising in the absence of injury
• chest pain or leg pain
• shortness of breath

**Other side effects are given below**
It is important to note that a small number of patients with multiple myeloma may develop additional types of cancer, and it is possible that this risk may be increased with Revlimid treatment, therefore your doctor should carefully evaluate the benefit and risk when you are prescribed Revlimid.
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
- Constipation, diarrhoea, nausea, redness of skin, rashes, vomiting, muscle cramps, muscle aches, bone pain, joint pain, tiredness, generalised swelling including swelling of the limbs
- Fever and flu like symptoms including fever, muscle ache, headache, earache and chills
- Numbness, tingling or burning sensation to the skin, pains in hands or feet, dizziness, tremor, taste disturbance
- Decreased appetite
- Low levels of potassium in the blood
- 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
- Infection of the lung and the upper respiratory tract, shortness of breath
- Blurred vision
- Headache
- Dry skin
- Abdominal pain

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

- Infection of the sinuses that surround the nose
- Bleeding from the gums, stomach, or bowels
- Increased blood pressure or a fall in blood pressure, slow, fast or irregular heart beat
- Increased pigmentation of skin
- Skin eruptions, skin cracking, flaking or peeling skin
- Hives, itching, increased sweating, dehydration
- Sore inflamed mouth, dry mouth, difficulty swallowing
- Heartburn
- Production of much more or much less urine than usual (which may be a symptom of kidney failure), passing blood in the urine
- Shortness of breath especially when lying down (which may be a symptoms of heart failure)
- Difficulty in obtaining an erection
- 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)
- Stroke, fainting
- Muscle weakness
- Joint swelling
- Changes to blood thyroid hormone, low levels of calcium, phosphate or magnesium in the blood
- Depression
- Cataract
- Reduced vision
- Deafness
- Abnormal liver test results
- Impaired balance, movement difficulty
- Ringing in the ears (tinnitus)
- Iron overload
- Thirst
- Mood change
- Confusion
• Toothache
• Weight loss

**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 amount of urine with bone pain and weakness, which may be symptoms of a kidney disorder (Fanconi syndrome)
• Inflammation of the large intestine (colitis and caecitis), both of which may be manifested as abdominal pain, bloating, or diarrhoea
• Renal tubular necrosis (a type of kidney impairment) which may be evident by production of much more or much less urine than usual
• Skin discolouration, sensitivity to sunlight
• Certain types of skin tumour
• Types of allergic reaction that may be manifested as hives, rashes, swelling of eyes, mouth or face, difficulty breathing, or itching (hypersensitivity/angioedema)

**Rare** side effects may affect up to 1 in 1,000 people:
• Serious allergic reaction that may begin as rash in one area but spread with extensive loss of skin over the whole body (Stevens-Johnson syndrome and/or toxic epidermal necrolysis).
• 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.

**Not known**: frequency cannot be estimated from the available data:
• Sudden, or mild but worsening pain in the upper abdomen 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.
• Yellow pigmentation to the skin, mucus membrane or eyes (jaundice), pale coloured stools, dark coloured urine, skin itch, rash, pain or swelling of the abdomen –these may be symptoms of injury to the liver (hepatic disorder).
• 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 administered with a statin (a type of cholesterol lowering medication).
• 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 intestine. This may lead to very serious infection. Tell your doctor if you have severe abdominal pain, fever, nausea, vomiting, blood in your stool, or changes in bowel habits.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. 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](http://www.mhra.gov.uk/yellowcard) (Freephone 0808 100 3352). By reporting side effects you can help provide more information on the safety of this medicine.

5. **How to store Revlimid**

- 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 after “EXP”. The expiry date refers to the last day of that month.
- 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. All unused Revlimid capsules should be returned to the pharmacist. These measures will help protect the environment.

6. **Content of the pack and other information**

**What Revlimid contains**

Revlimid 2.5 mg hard capsules:
- The active substance is lenalidomide. Each capsule contains 2.5 mg of lenalidomide.
- The other ingredients are:
  - capsule contents: lactose, anhydrous; cellulose, microcrystalline; croscarmellose sodium and magnesium stearate
  - capsule shell: gelatine, titanium dioxide (E171), indigo carmine (E132) and yellow iron oxide (E172)
  - printing ink: shellac, propylene glycol, potassium hydroxide and black iron oxide (E172).

Revlimid 5 mg hard capsules:
- The active substance is lenalidomide. Each capsule contains 5 mg of lenalidomide.
- The other ingredients are:
  - capsule contents: lactose, anhydrous; cellulose, microcrystalline; croscarmellose sodium and magnesium stearate
  - capsule shell: gelatine and titanium dioxide (E171)
  - printing ink: shellac, propylene glycol, potassium hydroxide and black iron oxide (E172).

Revlimid 10 mg hard capsules:
- The active substance is lenalidomide. Each capsule contains 10 mg of lenalidomide.
- The other ingredients are:
  - capsule contents: lactose, anhydrous; cellulose, microcrystalline; croscarmellose sodium and magnesium stearate
  - capsule shell: gelatine, titanium dioxide (E171), indigo carmine (E132) and yellow iron oxide (E172)
  - printing ink: shellac, propylene glycol, potassium hydroxide and black iron oxide (E172).

**What Revlimid looks like and contents of the pack**

Revlimid 2.5 mg hard capsules are blue-green/white, with “REV 2.5 mg” written on them. The capsules are provided in packs. Each pack contains one or three blisters, each blister with seven capsules. This gives a total of 7 or 21 capsules per pack.
Revlimid 5 mg hard capsules are white, with “REV 5 mg” written on them. The capsules are provided in packs. Each pack contains one or three blisters, each blister with seven capsules. This gives a total of 7 or 21 capsules per pack.

Revlimid 10 mg hard capsules are blue-green/pale yellow, with “REV 10 mg” written on them. The capsules are provided in packs. Each pack contains three blisters, each blister with seven capsules. This gives a total of 21 capsules per pack.

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United Kingdom

Marketing Authorisation Holder
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This leaflet was last revised in 09/2014

Other sources of information:

Please contact the Marketing Authorisation Holder if you require this information in another format.

Detailed information on this medicine is available on the website of the European Medicines Agency: http://www.ema.europa.eu/.

There are also links to other websites about rare diseases and treatments.