REVLIMID® CAPSULE

Lenalidomide (5mg, 10mg, 15mg, 25mg)

What is in this leaflet

What Revlimid® is used for

What is Revlimid®
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
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 in people who have already had one or more other types of treatment before.

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'.

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.

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

Before you use Revlimid®

- *When you must not use it*

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 below 'Before you start to use it' and 'While you are using it').
- if you are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see below 'Before you start to use it' and 'While you are using it'). 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 'Ingredients'. 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®.

- *Before you start to use it*

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.

You should tell your doctor if you are using implants and levonorgestrel-releasing intrauterine systems as they are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding.

For men taking Revlimid®
Revlimid® passes into human semen. If your female partner is pregnant or able to become pregnant, and she doesn't use effective methods of contraception, you must use condoms during treatment and 4 weeks after the end of treatment.

All individuals
Before starting the treatment, you should tell your doctor if you had blood clots or taking combined oral contraceptive pills in the past. During the treatment with Revlimid® you have an increased risk of developing blood clots in the blood vessels.

Please also inform your doctor if you have the following conditions: Kidney impairment, underactive thyroid, severe skin reaction, liver disorder.

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.

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

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down and cause unusual levels of chemicals in the blood which can lead to kidneys failure (this condition is called Tumour Lysis Syndrome).
- had an allergic reaction whilst taking thalidomide such as rash, itching, swelling, dizziness or trouble breathing.

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

- *Taking other medicines*

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 their effectiveness may be reduced.
- some medicines used for heart problems – such as digoxin
- some medicines used to thin the blood – such as warfarin

Other medicines not listed above may also interact with Revlimid. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Revlimid.

How to use Revlimid®

- *How much to use*

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

Revlimid® is taken in combinationwith dexamethasone. Always take Revlimid® and dexamethasone 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.

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 'Before you use 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 40mg 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.

- *When to use it*

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.

- *How long to use it*

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 forget to use it*

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 use too much* (overdose)

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

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

While you are using it

- *Things you must do*

For women taking 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®
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.

- *Things you must not do*

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.

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

You should not donate blood during treatment and for 4 weeks after the end of treatment.

- *Things to be careful of*

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

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

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 and flu like symptoms including fever, chills, sore throat, muscle ache, headache, 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 people 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 which 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, rashes, vomiting, muscle cramps, muscle aches, bone pain, tiredness, generalised swelling including swelling of the limbs
- 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)
- Infection of the lung and the upper respiratory tract, shortness of breath
- Blurred vision
- Headache

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (*Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety*).

Storage and disposal of Revlimid®

- *Storage*

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 store this medicine above 25°C.

Do not use this medicine if you notice any damage or signs of tampering to the pack.

- *Disposal*

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.

Product description

- *What it looks like*

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

White to off-white, opaque hard gelatin capsule with a black imprint, contains white to off-white to pale-yellow powder.

Revlimid® 5 mg hard capsules: Black imprint "REV 5mg"
Revlimid® 10 mg hard capsules: Black imprint "REV 10mg"
Revlimid® 15 mg hard capsules: Black imprint "REV 15mg"
Revlimid® 25 mg hard capsules: Black imprint "REV 25mg"

- *Ingredients*
- Active Ingredients

Lenalidomide

Inactive ingredients
- Capsule contents: anhydrous lactose, microcrystalline cellulose, croscarmellose sodium and magnesium stearate
- Printing ink: shellac, propylene glycol, potassium hydroxide and black iron oxide (E172).

Revlimid® 5 mg hard capsules:
- Capsule shell: gelatin and titanium dioxide (E171)

Revlimid® 10 mg hard capsules:
- Capsule shell: gelatin, titanium dioxide (E171), indigo carmine (E132) and yellow iron oxide (E172)

Revlimid® 15 mg hard capsules:
- Capsule shell: gelatin, titanium dioxide (E171) and indigo carmine (E132)

Revlimid® 25 mg hard capsules:
- Capsule shell: gelatin and titanium dioxide (E171).

- *MAL numbers*

Penn Pharmaceutical Services Limited
MAL20091851ACRZ (5mg)
MAL20091852ACRZ(10mg)
MAL20091853ACRZ(15mg)
MAL20091854ACRZ(25mg)

Celgene International Sarl
MAL12040005ARSZ(5mg)
MAL12040006ARSZ(10mg)
MAL12040004ARSZ(15mg)
MAL12040007ARSZ(25mg)

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