REVLIMID®

(lenalidomide)

New Zealand Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about REVLIMID. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking REVLIMID against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT REVLIMID IS USED FOR

REVLIMID contains an active substance called lenalidomide. REVLIMID belongs to a group of medicines called immunomodulating agents that work by acting on the cells involved in the body's immune system. The immune system is part of the body's defence which helps to fight illness and infection.

Treatment of Multiple Myeloma

Multiple myeloma (MM) is a cancer of the bone marrow.

- REVLIMID is used to treat adult patients who have been diagnosed with newly diagnosed Multiple Myeloma (NDMM) and who have undergone a stem cell transplant.
- REVLIMID is used in combination with another medicine called dexamethasone to treat adult NDMM patients who are not eligible for stem cell transplantation.
- REVLIMID is also used in combination with dexamethasone to treat adult MM patients whose disease has progressed after one therapy.

Treatment of Myelodysplastic Syndromes

REVLIMID is also used to treat patients who have conditions called myelodysplastic syndromes (MDS) in whom the bone marrow does not produce enough mature blood cells. This causes a lack of healthy blood cells in the body. There are different types of MDS.

REVLIMID is approved to treat a type of MDS where part of chromosome 5 is missing. This type of MDS is known as deletion 5q MDS (or 5q minus). Patients with this type of MDS often have low red blood cell counts that require treatment with blood transfusions. It is hoped that the use of REVLIMID will reduce the need for blood transfusions.

Ask your doctor if you have any questions about how REVLIMID works, or why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

REVLIMID will only be prescribed to you by a doctor who has experience in medicines to treat cancers of the blood.

BEFORE YOU TAKE REVLIMID

When you must not take it:

Do not take this medicine if you are pregnant, or think that you may be pregnant, or planning to become pregnant.

REVLIMID may cause birth defects (deformed babies), and may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are able to become pregnant, unless you are willing to follow the required pregnancy prevention measures (outlined in *i-access*® Program – see section 'Before you start to take it').

If you are not sure whether you should start taking this medicine, talk to your doctor.

Do not take REVLIMID if you have an allergy to lenalidomide or any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic response may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If you think you may be allergic to REVLIMID, ask your doctor for advice.

Before you start to take it:

Follow your doctor's instructions carefully.

You will have been given specific instructions by your doctor particularly on the potential effects of lenalidomide on unborn babies.

If you have not fully understood these instructions, ask your doctor again before taking REVLIMID.

Your doctor will have enrolled you in the *i-access* Program to ensure that lenalidomide is used safely.

The *i-access* Program

REVLIMID (lenalidomide) is structurally related to 'thalidomide', which is known to cause severe life-threatening human birth defects (deformed babies) and can cause death to an unborn baby if taken during pregnancy. If REVLIMID is taken during pregnancy, it may cause birth defects or death to an unborn baby.

To avoid exposure to unborn babies, REVLIMID is available only under a special distribution program called the *i-access* Program. This program is designed to ensure that REVLIMID is always prescribed and taken in the recommended way. Importantly, only patients who are formally enrolled in this program and agree to fully comply with all the requirements of this program can receive REVLIMID.

Some of the requirements of the *i-access* Program are outlined in the following sections. Your doctor will discuss all the details with you.

1. For women taking REVLIMID

Before starting this treatment, your doctor will discuss your potential to become pregnant, even if you think this is unlikely e.g. if your periods have stopped.

If you are able to become pregnant:

- Your doctor will discuss the potential risk to unborn babies if REVLIMID is taken during pregnancy.
- You will be required to have pregnancy tests before treatment, every 4 weeks during treatment, and 4 weeks after stopping treatment.
- You should start your REVLIMID treatment as soon as you get it from the pharmacy following a negative pregnancy test.
- **Use reliable means of contraception for at least 4 weeks before starting REVLIMID treatment, during treatment and treatment interruption, and for at least 4 weeks after REVLIMID treatment has stopped.**

  Your doctor will tell you what method of contraception to use.

Effective methods of contraception include the following:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal ligation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e. desogestrel).

Combined oral contraceptive pills are not recommended as they can increase the risk of blood clots blocking blood vessels in patients with MM being treated with this medicine.

You must stop taking REVLIMID and inform your doctor straight away if:

- You miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- You have heterosexual intercourse without using reliable means of contraception.

Discuss with your doctor if you should breast-feed whilst taking this medicine.

It is not known if REVLIMID is excreted in human milk. Therefore, you should discuss with your doctor whether to discontinue breast-feeding while you are receiving this medicine.

2. For men taking REVLIMID

Before starting this treatment, discuss with your doctor if your partner is able to become pregnant.

If your partner is able to become pregnant, use barrier methods of contraception (e.g. condoms) even if you are vasectomised, during REVLIMID treatment, during treatment interruption, and for at least 1 week after treatment has stopped.

Tell your doctor immediately if your partner becomes pregnant whilst you are taking this medicine.

Do not donate semen during treatment or during treatment interruption, or for 1 week after stopping treatment.

3. For all patients taking REVLIMID

Discuss with your doctor if you have or have had any of the following medical conditions:

- Blood clots, high blood pressure or high cholesterol
- Frequent bleeding or bruising
- Frequent infections
- Hepatitis B virus infection
- Peripheral neuropathy (numbness, tingling, weakness, abnormal co-ordination or pain in your hands and feet)
- Thyroid problems
- Abnormal kidney function
- Liver problems e.g. liver infections
- Allergic reactions to thalidomide or lenalidomide.

If you have not told your doctor about any of the above, tell him/her before you start taking REVLIMID.

Do not donate blood during REVLIMID treatment or during treatment interruption, and for at least 1 week after stopping treatment.

In New Zealand, patients with certain cancers may be excluded from donating blood.

Do not take REVLIMID if you have the rare hereditary problems of glucose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

REVLIMID contains lactose.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Your doctor will ask you to have regular blood tests during treatment with REVLIMID.

Your doctor should ask you to have a blood test every week for the first 8 weeks of treatment with REVLIMID and 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. If you are older than 65 years, in addition to these blood tests, your doctor may also check your kidney function with other tests.

Do not give this medicine to a child or adolescent under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established**.**

It is important to note that a small number of patients with MM may develop additional types of cancer (regardless of their type of therapy). At this stage, it cannot be excluded that this risk may be slightly increased with REVLIMID treatment. Therefore, your doctor will carefully evaluate the benefit and risk when you are prescribed this medicine.

Taking other medicines:

Tell your doctor or pharmacist if you are taking any other medicines or have recently taken any other medicines, including any medicines that you buy without a prescription from a pharmacy, supermarket or health-food shop.

Some medicines and REVLIMID may interfere with each other. These include:

- medicines used to prevent pregnancy, such as oral contraceptives
- medicines used to treat symptoms of menopause e.g. hormone replacement therapy
- medicines used for heart problems e.g. digoxin
- medicines used to thin the blood e.g. warfarin.

HOW TO TAKE REVLIMID

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

How much to take:

Your doctor will tell you how much REVLIMID to take and for how long you will need to take it.

For the treatment of NDMM after a stem cell transplant, the usual starting dose is 10 mg once daily.

For the treatment of MM in combination with dexamethasone (either NDMM in patients not eligible for stem cell transplantation or MM in patients whose disease has progressed after one therapy), the usual starting dose is 25 mg once per day for 21 out of 28 days.

For the treatment of MDS, the recommended starting dose is 10 mg once per day for 21 out of 28 days.

Your doctor will monitor your progress, and may adjust your dose of REVLIMID or stop your treatment based on the results of your blood tests and on your general condition.

How to take it:

Swallow the capsules whole, preferably with water, once a day as directed by your doctor.

Do not open, break or chew the capsules.

If powder from inside the capsules leaks out and contacts the skin, wash the skin immediately and thoroughly with soap and water. If lenalidomide contacts the mucous membranes e.g. the eyes, flush thoroughly with water.

When to take it:

Take your medicine either one hour before or two hours after eating food.

How long to take it:

Your doctor will tell you how long to continue taking REVLIMID.

Continue taking REVLIMID at about the same time each day for 21 days in a row and stop taking REVLIMID for the next 7 days. Repeat taking REVLIMID for 21 days and stopping for 7 days until your doctor tells you to stop.

If you forget to take REVLIMID:

If it is less than 12 hours before your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much REVLIMID (overdose):

In New Zealand, immediately telephone your doctor or contact the National Poisons Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to the Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much REVLIMID.

In Australia, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much REVLIMID.

Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

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

WHILE YOU ARE TAKING REVLIMID

Things you must do:

Female patients:

- **Tell your doctor immediately if you become pregnant or suspect that you may be pregnant. You should also immediately stop taking REVLIMID in this case.**

All patients:

- **Tell any other doctors, dentists, and pharmacists who are treating you that you are taking REVLIMID.**
- **If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking REVLIMID.**
- **Keep all of your doctor's appointments so that your progress can be checked.**

  Your doctor will do some blood tests regularly and will check your general condition to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do:

Female patients:

- **Do not become pregnant whilst taking REVLIMID.**
- **Do not have sexual intercourse without using effective means of contraception described to you by your doctor.**

Male patients:

- **Do not donate sperm during treatment or treatment interruption, or for at least 1 week after stopping treatment.**
- **Do not have sexual intercourse without using effective means of contraception described to you by your doctor.**

All patients:

- **Do not donate blood during treatment or treatment interruption, or for at least 1 week after stopping treatment.**

  In New Zealand, patients with some types of cancer may be excluded from donating blood.
- **Do not stop taking REVLIMID (unless you suspect that you are pregnant) or change the dose without first checking with your doctor.**
- **Do not let yourself run out of medicine over the weekend or on holidays.**
- **Do not give this medicine to anyone else, even if they have the same condition as you.**
- **Do not take this medicine to treat any other complaints unless your doctor or pharmacist tells you to.**
- **Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

  In that case, return it to your pharmacist.

Things to be careful of:

Be careful driving or operating machinery until you know how REVLIMID affects you.

This medicine may cause dizziness, tiredness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking REVLIMID.

Like all medicines, REVLIMID can have side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- Diarrhoea; constipation; feeling sick (also called nausea); vomiting; stomach pain; indigestion; dehydration; dry mouth; toothache; increase or decrease in weight; increase or decrease in appetite; loss of taste.
- Itchiness; rash; redness of the skin; dry skin; excessive sweating.
- Dizziness; fainting; headache; shaking or tremors; reduced sense of touch.
- Difficulty sleeping; depression; anxiety; feeling of confusion.

- Back pain; muscle spasms; muscle and/or joint pain; swollen joints; bone pain; muscular weakness; fall.
- Swelling of hands, ankles or feet.

The above list mainly includes the more common side effects of your medicine.

Tell your doctor immediately if you notice any of the following:

- **Bleeding (including nose-bleeds) or bruising more easily than normal.**

  REVLIMID can reduce the number of platelets, which are responsible for making the blood clot properly. Your doctor may monitor your blood cell numbers during treatment with REVLIMID.
- **Tiredness, headaches, shortness of breath, dizziness and looking pale.**

  REVLIMID can reduce the number of red blood cells that carry oxygen around the body.
- **Numbness, tingling, or weakness of the arms and legs.**

  This may be due to nerve damage.
- **Blurred vision or difficulty seeing.**

  This could be due to a cataract in your eye(s).
- **Passing large amounts of urine, excessive thirst, and having a dry mouth and skin.**

  These could be symptoms of diabetes.
- **Abnormal eye movements, convulsions, or irregular heart rhythms.**

  These could be due to low levels of minerals such as potassium, calcium, magnesium or sodium.

The above list includes serious side effects that may require medical attention.

If any of the following happens, stop taking REVLIMID and see a doctor immediately or go to Accident and Emergency at your nearest hospital:

- **Shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, mouth, tongue or other parts of the body; rash, itching or hives on the skin.**

  These could be symptoms of an allergic reaction.
- **Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals; painful red area on the skin that spreads quickly; peeling of the skin. You may have a high temperature, chills and muscle ache at the same time.**

  These could be due to rare but severe skin reactions such as Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis and Drug Reaction with Eosinophilia and Systemic Symptoms.
- **Blurred vision; severe headache; weakness or numbness in the face, arm or leg; trouble speaking or understanding; loss of balance.**

  This may be due to a stroke which could be a result of blood clots in the blood vessels of your brain.
- **Sudden pain in your chest or difficulty in breathing.**

  This may be due to a heart attack or blood clots in the artery leading to your lungs. These blood clots can happen during treatment, or after treatment has stopped.
- **Pain or swelling in your legs, especially in your lower leg or calves.**

  This may be due to blood clots in the veins of your leg. These can happen during treatment, or after treatment has stopped.
- **Fever; severe chills; decreased urination; rapid pulse; rapid breathing; confusion; nausea; vomiting; diarrhoea; pain or burning when you urinate; hacking cough; phlegm; sore mouth or throat; flu-like symptoms; feeling of tension in the nose, cheeks and behind your eyes; or mouth ulcers.**

  These could symptoms of sepsis (blood infection) or other serious infections such as pneumonia.
- **Passing little or no urine; drowsiness; nausea; vomiting; or breathlessness.**

  These could be symptoms of kidney disease.
- **Abdominal pain, dark urine, fever, joint pain, loss of appetite, nausea and vomiting, yellowing of the skin and/or eyes.**

  These are symptoms of liver failure, which in some cases, may be due to Hepatitis B virus infection. Some cases of Hepatitis B virus infection may not result in symptoms initially.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist immediately if any of the side effects gets serious, or if you notice any other side effects not listed in this leaflet.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, changes in thyroid function, or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

AFTER TAKING REVLIMID

Storage

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Keep your capsules in the original package until it is time to take them.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, take any unused REVLIMID capsules to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

PRODUCT DESCRIPTION

What REVLIMID looks like:

The capsules are provided in packs. There are two (2) pack sizes available. A pack will contain either three blisters, each with seven capsules, giving a total of twenty-one (21) capsules per pack or four blisters, each with seven capsules, giving a total of twenty-eight (28) capsules per pack. Some strengths of REVLIMID may not be available as not all strengths are being distributed.

REVLIMID 2.5 mg capsules have a white body/blue-green opaque cap with “2.5 mg REV” written on them.

REVLIMID 5 mg capsules are white to off-white opaque capsules with "5 mg REV" written on them.

REVLIMID 7.5 mg capsules have a white body/pale yellow opaque cap with “7.5 mg REV” written on them.

REVLIMID 10 mg capsules are pale yellow opaque body/blue-green opaque cap capsules with "10 mg REV" written on them.

REVLIMID 15 mg capsules are white to off-white opaque body / powder-blue opaque cap capsules with "15 mg REV" written on them.

REVLIMID 20 mg capsules have a powder blue body/blue-green opaque cap with “20 mg REV” written on them.

REVLIMID 25 mg capsules are white to off-white opaque capsules with "25 mg REV" written on them.

Ingredients

REVLIMID capsules contain an active ingredient called lenalidomide.

The other ingredients are:

- lactose,
- microcrystalline cellulose,
- croscarmellose sodium, and
- magnesium stearate.

The capsule shell contains gelatine and titanium dioxide, and the following colourants for 10 mg capsules: FD&C blue #2 (E132) and yellow iron oxide (E172).

The printing ink contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, purified water, strong ammonia solution, potassium hydroxide, and black iron oxide (E172).

SPONSOR DETAILS

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