

Patient Booklet

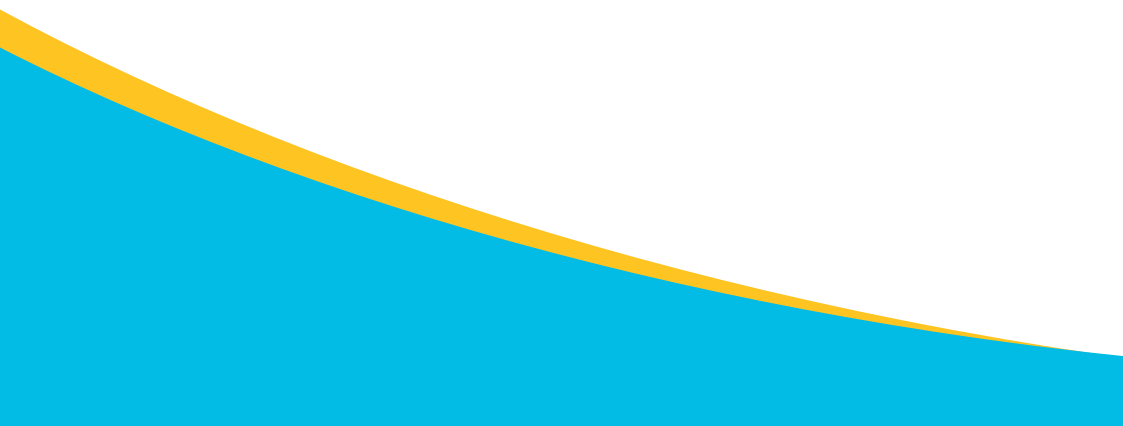
Treatment with Revlimid®▼ (lenalidomide)
for
Multiple Myeloma





Contents

Summary	3
Safety information for all patients	4
Information for women who are able to become pregnant	7
Information for women who are not able to become pregnant	9
Information for men	11
What should you tell your doctor before taking Revlimid	12
How to take your medication	13
End of Treatment Requirements	15
Additional information	16



Summary

- Revlimid is the trade name for lenalidomide
- Revlimid is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects
- An unborn child would be likely to be harmed if exposed to Revlimid during pregnancy
- Revlimid must never be taken by a woman who is pregnant or who could become pregnant
- Men taking Revlimid must use a condom during sexual contact with a woman who is able to become pregnant and who does not use effective contraception
- People taking Revlimid must not donate blood while they are taking Revlimid or for 1 week after stopping
- Revlimid must never be shared with anyone else
- Unused Revlimid capsules must be returned to a pharmacy for safe disposal as soon as possible.

You **must** contact your hospital team **urgently** if you suspect that you or your partner is pregnant.

Like all medicines Revlimid can cause side-effects, although not everybody gets them. Some are more common than others and some are more serious than others. If you notice any of the problems below you must contact your doctor or hospital team immediately (you will find more details on these, and other side-effects in this brochure).

You **must** contact your hospital team **urgently** if you feel unwell or develop any of the following:

- Fever (temperature greater than 38°C (100°F))
- Shivering episodes or flu-like symptoms
- Gum/nose bleeds or unusual bruising
- Chest pain or difficulty breathing
- Pain or swelling in your arms or legs
- Any other symptom that causes concern.

Please ask your doctor or nurse if you need more information or an explanation of any of the terms used in this booklet.

Safety information for all patients

You must never take Revlimid if:

- You are pregnant
- You are breastfeeding
- You are a woman who is able to become pregnant, even if you are not planning to become pregnant. Women able to become pregnant must use an effective form of contraception for 4 weeks before starting Revlimid, throughout the duration of the treatment and for 4 weeks after stopping treatment
- You are allergic to Revlimid or to any of the other ingredients contained in the capsule.

Revlimid would be harmful to an unborn baby

- Revlimid is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects
- An unborn child would be likely to be harmed if exposed to Revlimid during pregnancy.

Women

If Revlimid is taken during pregnancy, severe, life-threatening birth defects are expected. If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant you must not take Revlimid. Even if you are not having regular periods or are approaching the menopause you may still be able to become pregnant.

If for any reason you think you may be pregnant while you are taking Revlimid, or in the 4 weeks after stopping, you must immediately stop taking Revlimid and contact your doctor.

Men

Revlimid is present in human semen. Men taking Revlimid must use a condom every time they have intercourse with a woman who is able to become pregnant.

You must contact your hospital team or doctor urgently if you suspect that your partner may be pregnant while you are taking Revlimid, or in the 4 weeks after you stop.

Side effects

Like all medicines, Revlimid can cause side-effects, although not everybody gets them. Some are more common than others and some are more serious than others. These are not all the side-effects that have been reported with Revlimid. Ask your doctor or pharmacist if you would like more information.

Almost all side-effects are temporary and can be easily prevented or treated. The most important thing is to be aware of what to expect and what to report to your doctor.

It is important that you talk to your doctor if you have any side-effects during Revlimid treatment. You may also report any side-effect to the UK Medicines and Healthcare products Regulatory Agency via their 'Yellow Card' scheme, by using their web site at www.yellowcard.gov.uk.

Serious side-effects and what to look out for:

Low white blood cells and platelets

Revlimid may cause a drop in the number of white blood cells in your blood. This can make you more prone to infections. You may be prescribed treatments to prevent infections or to boost your blood counts. Revlimid may also cause a drop in the number of platelets in your blood. If the count drops too low you may be at risk of bleeding.

You should contact your doctor immediately if you experience any of the following:

- Symptoms of infection such as: fever (temperature greater than 38°C (100°F)), shivering episodes or flu-like symptoms, chills, sore throat, cough, or any other symptoms suggestive of infection
- Gum or nose bleeds
- Bruising or bleeding that happens without being injured.

Blood clots in veins and in the lungs

Revlimid treatment may increase the risk of you developing blood clots in some veins in the body. This is sometimes called deep vein thrombosis (DVT). People with myeloma may already have a higher risk of blood clots. Symptoms of a blood clot can be leg pains, swelling and redness of the lower legs or arms. Sometimes the clots can travel in your bloodstream to your lungs producing symptoms of chest pain and breathlessness. You may be prescribed treatment to help prevent blood clots from forming.

You should contact your doctor immediately if you experience any of the following:

- chest pain or difficulty breathing
- pain or swelling in your arms or legs
- any other symptom that causes concern.

Other common side-effects with Revlimid are:

- muscle cramps or weakness
- diarrhoea
- constipation
- nausea (feeling sick)
- tiredness
- difficulty sleeping
- changes in body weight.

Remember, almost all side-effects are temporary and can be easily prevented or treated. If you experience any side-effect that causes you concern, contact your doctor or hospital team.

Special monitoring

Because Revlimid can cause a drop in white blood cell and platelet counts you will have regular blood tests during treatment. Your doctor will also monitor how well your kidneys are working. You will have blood tests more frequently in the first few months when you start treatment.

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 treatment has to be stopped for any reason your doctor will discuss other treatment options with you.

Information for women who are able to become pregnant

Revlimid would be harmful to an unborn baby

- Revlimid is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects
- An unborn child would be likely to be harmed if exposed to Revlimid during pregnancy
- If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant you must not take Revlimid
- Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant
- Every woman who is able to become pregnant, even if they are not planning to, must follow the precautions detailed in this section, designed to prevent you becoming pregnant, and to ensure you are not pregnant. By signing your treatment consent form you are agreeing to follow these precautions
- You should start your Revlimid treatment as soon as possible after having a negative pregnancy test result.

If for any reason you think you may be pregnant while you are taking Revlimid, or in the 4 weeks after stopping, you must immediately stop taking Revlimid and contact your doctor.

Before starting Revlimid treatment you should discuss with your doctor whether or not there is any possibility that you could become pregnant. Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant.

Unless you fall into one of the following categories you must follow the pregnancy prevention advice presented in this section:

- You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy, then there is still a chance you could become pregnant)
- Your womb has been removed (hysterectomy)
- Your fallopian tubes and both ovaries have been removed (bilateral salpingo oophorectomy)
- You have premature ovarian failure, confirmed by a specialist gynaecologist
- You have the XY genotype, Turner's syndrome or uterine agenesis

You may need an appointment and tests with a specialist in female medicine to confirm that you cannot become pregnant. Every woman who is able to become pregnant even if they are not planning to must follow the precautions detailed in this section.

Contraception to prevent pregnancy

If you are a woman who could become pregnant you must either:

- Use adequate contraception starting 4 weeks before Revlimid treatment, during Revlimid treatment, during any breaks in Revlimid treatment and for 4 weeks after stopping Revlimid treatment

Or

- Agree you will not engage in sexual activity with a male partner starting 4 weeks before Revlimid treatment, during Revlimid treatment, during any breaks in Revlimid treatment and for 4 weeks after stopping Revlimid treatment. You will be asked to confirm this every month.

Not all types of contraception are suitable during Revlimid treatment. You and your partner should discuss with your doctor suitable forms of contraception that you both find acceptable. If necessary, your hospital team can refer you to a specialist for advice on contraception.

Pregnancy tests to ensure you are not pregnant

- If you are a woman who could become pregnant you must have a pregnancy test to make sure you are not pregnant before you start Revlimid treatment
- You must also have a pregnancy test every 4 weeks during your treatment, to make sure you are not pregnant
- Your next prescription for Revlimid cannot be dispensed until it is confirmed that you are not pregnant
- Pregnancy tests must be overseen by a doctor or nurse looking after you
- If you have had surgery to stop you becoming pregnant (tubal sterilisation) you do not need to have pregnancy tests.

To ensure that an unborn baby is not exposed to Revlimid your doctor will complete a Prescription Authorisation Form with each prescription. The form documents that you have given consent for Revlimid treatment and have been told about the risks to an unborn baby and the precautions you must take.

You must ensure that you receive your Revlimid within 7 days of it being prescribed or you will need a new prescription.

Information for women who are not able to become pregnant

Revlimid would be harmful to an unborn baby

- Revlimid is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects
- An unborn child would be likely to be harmed if exposed to Revlimid during pregnancy

- Before starting Revlimid treatment you should discuss with your doctor whether or not there is any possibility that you could become pregnant
- Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant
- You may need an appointment and tests with a specialist in female medicine to confirm that you cannot become pregnant
- Every woman who is able to become pregnant even if they are not planning to must follow the precautions detailed in the section 'Information for women who are able to become pregnant'.

You are considered to be a women who is not able to become pregnant if you fall into one of the following categories:

- You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy, then there is still a chance you could become pregnant)
- Your womb has been removed (hysterectomy)
- Your fallopian tubes and both ovaries have been removed (bi-lateral salpingo oophorectomy)
- You have premature ovarian failure, confirmed by a specialist gynaecologist
- You have the XY genotype, Turner's syndrome or uterine agenesis.

To ensure that an unborn baby is not exposed to Revlimid your doctor will complete a Prescription Authorisation Form with each prescription. The form documents that you have given consent for Revlimid treatment and have been told about the risks to an unborn baby and the precautions you must take.

You must ensure that you receive your Revlimid within 7 days of it being prescribed or you will need a new prescription.

Information for men

Revlimid would be harmful to an unborn baby

- Revlimid is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects
- An unborn child would be likely to be harmed if exposed to Revlimid during pregnancy
- Revlimid is present in human semen
- You must use a condom every time you have sexual contact with a woman who is pregnant or able to become pregnant and who does not use effective contraception
- Even if you have had a vasectomy you must use a condom throughout your Revlimid treatment, during any breaks in treatment and for 1 week after stopping treatment
- If your partner does become pregnant while you are taking Revlimid, you must contact your doctor immediately.

To ensure that an unborn baby is not exposed to Revlimid your doctor will complete a Prescription Authorisation Form with each prescription. The form documents that you have given consent for Revlimid treatment and have been told about the risks to an unborn baby and the precautions you must take.

You must ensure that you receive your Revlimid within 7 days of it being prescribed or you will need a new prescription.

What should you tell your doctor before taking Revlimid

- If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant, as Revlimid may be harmful to an unborn child
- If you think you are able to become pregnant and need advice on effective contraception
- If you are breastfeeding
- If you have previously had an allergic (hypersensitive) reaction to Revlimid
- If you have previously had an allergic (hypersensitive) reaction to any other ingredient in Revlimid capsules. Ask your pharmacist for advice
- If you have a history of kidney problems
- If you have a history of thrombosis (blood clots)
- If you are taking or have recently taken any other medicines, including medicines bought without a prescription.

How to take your medication

Your pharmacist can give you help and advice on taking your medicines. Some people find it helpful to mark on a calendar when they have taken their medicines each day or to set an alarm clock to remind them to take their medicines.

Revlimid

- Your doctor will prescribe a dose of Revlimid suited to you
- Revlimid is taken orally (by mouth) usually once each day for 21 days followed by a 7-day rest. The total 28 days is called a cycle
- Your doctor may adjust your dose depending on the result of blood tests and any side-effects you may experience
- Do not take more capsules than your doctor has prescribed. If in doubt, ask your doctor or pharmacist for advice
- Revlimid capsules should be swallowed whole, with a glass of water
- Revlimid can be taken at any time of day but it should be taken at approximately the same time each day
- Revlimid can be taken with or without food.

Dexamethasone

- Revlimid is licensed to be taken in combination with dexamethasone and therefore you are likely to receive both
- If you are also taking dexamethasone tablets you can take these at the same time as your Revlimid
- Dexamethasone is usually only taken for a few days each week. Follow the instructions from your doctor/pharmacist carefully
- Dexamethasone should, if possible, be taken with or after food in the morning.

What to do if you have taken more than the prescribed dose of Revlimid:

If you accidentally take too many capsules, contact your doctor immediately.

What to do if you forget to take your Revlimid:

If you forget to take your Revlimid and you remember within 12 hours of the missed dose you can take your Revlimid as soon as you remember and continue with the next dose at the normal time. If it is more than 12 hours since the missed dose, leave out that dose altogether and take the next dose at the normal time. Let your doctor know if you have missed any doses at your next visit.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines bought without a prescription. If you are seeing a different doctor or other healthcare professional for treatment (your dentist for example) you should tell them that you are taking Revlimid and dexamethasone.

How to store Revlimid safely

Keep your Revlimid in a safe place out of the reach and sight of children.

Keep your Revlimid capsules in the original box at room temperature.

Do not use after the expiry date written on the box.

End of Treatment Requirements

After completing your Revlimid treatment, it is important that:

- You return any unused Revlimid capsules to your pharmacist
- You do not donate blood for 1 week.

Additional advice for women who are able to become pregnant:

- Continue using your effective pregnancy prevention method for a further 4 weeks
- Your doctor will perform a final pregnancy test after 4 weeks.

Additional advice for male patients:

- If you have been using an effective pregnancy prevention method, you must continue doing so for 1 week
- If your female partner has been using an effective pregnancy prevention method, she must continue doing so for 4 weeks.

Additional information

What is multiple myeloma?

Myeloma is a type of cancer that affects plasma cells. Plasma cells are produced in the bone marrow and form part of the body's immune system. The function of the immune system is to fight disease and infection. Myeloma can occur in multiple parts of the bone marrow which is why it is often called multiple myeloma. Multiple myeloma that does not respond to or returns after initial treatment is referred to as relapsed or refractory multiple myeloma.

What is Revlimid?

Revlimid belongs to a group of medicines called immunomodulatory drugs or IMiDs. They work by modifying or regulating the immune system. Revlimid is licensed in Europe for use in combination with the steroid dexamethasone, for patients who have received at least one prior treatment for multiple myeloma. Revlimid is structurally related to thalidomide, which is known to cause severe, life-threatening birth defects. Precautions must be taken to avoid exposure to Revlimid in an unborn baby.

How can Revlimid help me?

In the main Revlimid clinical trials, all of the patients had multiple myeloma that had relapsed after at least one prior treatment. Revlimid was taken together with the steroid dexamethasone by one half of a group of patients, the other half took dexamethasone on its own. Almost 60% of the patients who took Revlimid with dexamethasone responded compared to around 25% of patients who took dexamethasone on its own. Their response was measured as a reduction in the amount of abnormal protein (paraprotein) in their blood or by their myeloma becoming stable. There are a number of treatments for multiple myeloma but not all will work for all patients.



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