PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

REVLIMID® 5 mg (Hard capsules)

REVLIMID® 10 mg (Hard capsules)

REVLIMID® 15 mg (Hard capsules)

REVLIMID® 25 mg (Hard capsules)

Read all of this leaflet carefully before you start taking Revlimid

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Revlimid** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WARNING: SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS.

Lenalidomide, the active ingredient contained in Revlimid, is structurally related to thalidomide, a substance that causes severe life-threatening birth defects. Lenalidomide showed malformations in monkeys, similar to those described with thalidomide (see 'Pregnancy and lactation'). If Revlimid is taken during pregnancy, the same effect can be expected in humans.

BECAUSE OF THIS TOXIC EFFECT AND IN AN EFFORT TO MAKE THE CHANCE OF EXPOSURE DURING PREGNANCY TO REVLIMID AS SMALL AS POSSIBLE, REVLIMID IS APPROVED FOR USE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAMME. THIS PROGRAMME IS CALLED THE KEY ASSIST RISK MANAGEMENT PROGRAM.

UNDER THIS RESTRICTED DISTRIBUTION PROGRAMME, ONLY DOCTORS REGISTERED WITH THE PROGRAMME ARE ALLOWED TO PRESCRIBE THE PRODUCT AND PHARMACISTS REGISTERED WITH THE PROGRAMME ARE ALLOWED TO DISPENSE THE PRODUCT. IN ADDITION, YOU MUST BE ADVISED OF, AGREE TO, AND COMPLY WITH THE REQUIREMENTS OF THE KEY ASSIST RISK MANAGEMENT PROGRAM.

WHAT REVLIMID CONTAINS:

The active substance is lenalidomide.

Each Revlimid 5 mg hard capsule contains 5 mg of lenalidomide

Each Revlimid 10 mg hard capsule contains 10 mg of lenalidomide

Each Revlimid 15 mg hard capsule contains 15 mg of lenalidomide

Each Revlimid 25 mg hard capsule contains 25 mg of lenalidomide

The other inactives are:

Lactose anhydrous, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate.

The 5 mg and 25 mg capsule shells contain gelatin, titanium dioxide (E171) and black ink*.

The 10 mg capsule shells contain gelatin, FD&C blue #2 (indigo carmine; E132), yellow iron oxide (E172), titanium dioxide (E171) and black ink*.

The 15 mg capsule shell contains gelatin, FD&C blue #2 (indigo carmine; E132), titanium dioxide (E171) and black ink*.

* Black ink contains shellac, black iron oxide (E172) and potassium hydroxide.

Contains sugar (lactose).

WHAT REVLIMID IS USED FOR:

Revlimid belongs to a group of medicines called immunomodulatory medicines, which can modify or regulate the functioning of the immune system.

- Revlimid in combination with dexamethasone is used to treat adult patients who have been diagnosed with multiple myeloma. Multiple myeloma is a type of blood cancer that affects the white blood cells that produce antibodies.
- Revlimid is also used to treat adult patients who have been diagnosed with myelodysplastic syndromes. Patients with myelodysplastic syndromes have an abnormality of their bone marrow, which means they don't make enough healthy blood cells.

BEFORE YOU TAKE REVLIMID:

Follow all of your doctor's instructions carefully, even if they differ from the general information given in this leaflet.

Your doctor will have enrolled you in the KEY ASSIST RISK MANAGEMENT PROGRAM to ensure that REVLIMID is used safely.

<u>Do not take Revlimid:</u>

- if you are pregnant or think you may be pregnant or are planning to become pregnant, **as Revlimid is harmful to an unborn child** (see sections: 'Take special care with Revlimid' and 'Pregnancy').
- if you are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see sections: 'Take special care with Revlimid' and 'Pregnancy'). 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 (hypersensitive) to lenalidomide or any of the other ingredients of Revlimid listed in the following Section: 'What Revlimid contains'. 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.

Take special care with Revlimid:

Please talk to your doctor in the following situations:

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 treatment, every 4 weeks during treatment, and 4 weeks after the treatment has finished) except in the case of confirmed tubal sterilisation
- and you must use two effective methods of contraception for 4 weeks before starting treatment, during treatment including dose interruptions 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 doesn't use effective methods of contraception, you must use condoms during treatment including dose interruptions and for 4 weeks after the end of treatment (even if you have undergone vasectomy).

Male patients taking Revlimid should not donate sperm or semen during treatment including dose interruptions and for 4 weeks following the end of treatment.

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 and help the blood to clot. Your doctor may 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 including dose interruptions and for 4 weeks after the end of treatment.

You should never to give Revlimid to another person. Return any unused capsules to your pharmacist at the end of treatment.

Taking other medicines with Revlimid:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.) Please consult your doctor, pharmacist or other healthcare professional, for advice.

Inform your doctor if you take:

- Warfarin (medicine to prevent blood clotting);
- Digoxin (medicine used to treat heart problems);
- Medicines that stimulate the production of red blood cells, or other agents that may increase the risk of blood clots (thrombosis), such as hormone replacement therapy.

Taking Revlimid with food and drink:

The Revlimid capsules can be taken either with or without food (see following Section: 'How to take Revlimid').

Pregnancy and breastfeeding:

Pregnancy:

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 two effective methods of contraception if you are a woman of childbearing potential (see Section: 'Take special care with 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, please see section: 'Take special care with 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.

Breastfeeding:

You should not breastfeed when taking Revlimid

Driving and using machines:

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

Important information about some of the ingredients of Revlimid:

Revlimid contains lactose (a type of sugar). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Revlimid.

HOW TO TAKE REVLIMID:

Revlimid is taken alone or in combination with dexamethasone. Always take Revlimid alone or Revlimid and dexamethasone in combination exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. You should refer to the package leaflet for dexamethasone for further information on its use and effects.

Your doctor will prescribe the correct dose for your condition.
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: ‘Take special care with 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.

If you have the impression that the effect of Revlimid is too strong or too weak, talk to your doctor or pharmacist.

Duration of the treatment with Revlimid:

Revlimid is taken in treatment cycles, each cycle lasting 28 days. You should continue the cycles of treatment until your doctor tells you to stop.

If you take more Revlimid than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take Revlimid:

If less than 12 hours has elapsed since missing a dose, you can take the dose. If more than 12 hours has elapsed since missing a dose at the normal time, you should not take the dose, but take the next dose at the normal time on the following day. Do not take 2 doses at the same time.

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

POSSIBLE SIDE EFFECTS:

Revlimid can cause side effects.

It is important to note that Revlimid may reduce the number of white blood cells that fight infection and also the blood cells which help the blood to clot (platelets). Revlimid may also cause blood clots in the veins (thrombosis).

Therefore **you** must **tell** your **doctor** immediately if you experience:

- any fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection;
- any bleeding or bruising in the absence of injury;

- any chest or leg pain;
- any shortness of breath.

It is important to note that 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.

If any of the following symptoms occur, it may be a serious allergic reaction. Stop taking Revlimid and tell your doctor immediately or go to the casualty department at your nearest hospital. You may need urgent medical attention or hospitalisation:

- An allergic reaction which may begin as rash in one area but spread with extensive loss of skin over the whole body.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Wheezing, shortness of breath or a dry cough, which may be symptoms caused by inflammation of the tissue in the lungs, may occur.

These are all serious side effects. You may need urgent medical attention.

Frequent side effects are given below. You should consult your doctor if you experience any of these:

- A fall in the number of white blood cells (the cells that fight infection), platelets (the cells that help the blood to clot, which may lead to bleeding disorders) and red blood cells (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, 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 blood clots (thrombosis)), chest pain or shortness of breath (which may be a symptom of blood clots in the lungs).
- Infection of the lung and the upper respiratory tract, shortness of breath, nosebleed.
- Blurred vision.
- Headache.
- Chest pain.
- Difficulty breathing.
- Infections of all types.
- Infection of the sinuses that surround the nose.
- Bleeding from the gums, stomach, or bowels, bruising.
- Increased blood pressure or a fall in blood pressure, slow, fast or irregular heart beat.
- Skin eruptions, skin cracking, flaking.
- Hives, itching, dry skin, increased sweating, dehydration.
- Sore inflamed mouth, dry mouth.
- Abdominal pain.
- Production of much more or much less urine than usual (which may be a symptom of kidney failure).
- 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.
- Low levels of calcium, phosphate or magnesium in the blood.
- Depression.
- Cataract.
- Reduced vision.
- Abnormal liver test results.
- Iron overload.
- Mood change.
- Toothache.

Less frequent side effects are given below. You should consult your doctor if you experience any of these:

- Bleeding in the brain.
- Circulatory problems.
- Certain types of cancer of the skin
- Hypersensitivity or an allergic reaction (angioedema), a type of allergic reaction that may have symptoms such as hives, rashes, swelling of eyes, mouth or face, difficulty of breathing, or itching.
- Tumour lysis syndrome - metabolic complications that can occur during treatment of cancer and sometimes even without treatment.

Side effects where the frequency is not known are given below. You should consult your doctor if you experience any of these:

- 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.

Not all side effects reported for Revlimid are included in this leaflet. Should your general health worsen while taking Revlimid, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF REVLIMID:

Keep all medicines out of the reach and sight of children.

Store at or below 25 ºC. Keep in the outer carton until required for use.

Do not store in bathrooms.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

PRESENTATION OF REVLIMID:

Clear, transparent Polyvinylchloride (PVC) / Polychlorotrifluoroethylene (PCTFE) / Aluminium foil blisters, each with seven capsules. There will be either 1, 3 or 4 blisters in each pack, dependant on pack size (either 7, 21 or 28 capsules), packed in a cardboard carton.

IDENTIFICATION OF REVLIMID:

Revlimid 5 mg hard capsules: White to off-white, opaque size 2 hard gelatin capsule with a black imprint of ‘REV’ and ‘5 mg’

Revlimid 10 mg hard capsules: Pale yellow opaque body, blue green opaque cap, size 0, hard gelatin capsule with a black imprint of ‘REV’ and ’10 mg’.

Revlimid 15 mg hard capsules: White to off-white opaque body, powder blue opaque cap, size 0, hard gelatin capsule with a black imprint of 'REV' and '15 mg'.

Revlimid 25 mg hard capsules: White to off-white, opaque size 0 hard gelatin capsule with a black imprint of 'REV' and '25 mg'.

REGISTRATION NUMBER:

Revlimid 5 mg: 47/32/0507

Revlimid 10 mg: 47/32/0508

Revlimid 15 mg: 47/32/0509

Revlimid 25 mg: 47/32/0510

NAME AND ADDRESS OF REGISTRATION HOLDER:

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