Patient Information Leaflet

Revlimid®

hard capsules (5, 10, 15 and 25 mg)
Lenalidomide

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Health Care Professionals are asked to report any suspected adverse reactions.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again
- If you have further questions, ask your doctor, health care provider or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist

In this leaflet:

1. What Revlimid is and what it is used for

On medical prescription.

Revlimid contains the active substance lenalidomide, which affects certain cells and substances of the immune system and thus leads to inhibition of the formation of malignant blood cells.

Revlimid is used in patients with multiple myeloma (a malignant disease with pronounced proliferation of certain cells in the bone marrow) as monotherapy, or in combination with other medicines.

Revlimid is used as monotherapy to treat adult patients with multiple myeloma who have undergone a bone marrow transplant.

Revlimid is used in combination with bortezomib (a so-called proteasome inhibitor) and dexamethasone (an anti-inflammatory drug) for the treatment of adult patients with newly diagnosed multiple myeloma.

For newly diagnosed multiple myeloma patients who cannot undergo a bone marrow transplant, there are two types of treatment:

- In the first treatment option Revlimid is used in combination with an anti-inflammatory medicine called 'dexamethasone'.
- In the second treatment option Revlimid is used in combination with a 'melphalan' (a chemotherapy medicine) and "prednisone' (an immunosuppressant medicine). You will take these other medicines at the start of treatment and then continue to take Revlimid on its own.

Multiple myeloma patients who have had at least one other type of treatment before Revlimid is taken together with an anti-inflammatory medicine called 'dexamethasone'.

Revlimid is used on its own for the treatment of adult patients in whom certain types of myelodysplastic syndrome (MDS) have been diagnosed. In patients with MDS the bone marrow does not form enough healthy blood cells in the body. Revlimid is used in certain types of MDS in which the patients have fewer red blood cells than normal, are dependent on blood transfusions and also have a certain chromosome mutation.

Revlimid is used in combination with rituximab to treat adult patients with previously treated follicular lymphoma (FL) in whom the disease has recurred or has not improved after previous treatment(s). FL is a slow-growing cancer of the B lymphocytes, a type of white blood cell that helps the body fight infection. If you suffer from FL, too many of these diseased B-lymphocytes can accumulate in your blood, bone marrow, lymph nodes and spleen, displacing your healthy cells.

Revlimid is used on its own in patients with reoccurring mantle cell lymphoma (a certain type of cancer in the lymph system), who have already previously received another therapy that included bortezomib and a chemotherapy together with Rituximab.

2. Before you take or use Revlimid

When must Revlimid not be used?

If you are pregnant or think you may be pregnant or are planning to become pregnant.

In women of childbearing age, unless strict contraceptive measuresare taken; see "When is caution indicated with the use of Revlimid?".

In cases of hypersensitivity to the active substance lenalidomide or to any of the inactive ingredients.

When is caution indicated with the use of Revlimid?

Revlimid is available only through a restricted distribution program, called the Lenalidomide i-SECURE program.

You will have been given specific instructions by your doctor, particularly on the effects of Revlimid on unborn babies (outlined in the *i-SECURE* program).

You will have been given a Revlimid *i-SECURE* patient brochure by your doctor. Read it carefully and follow the related instructions.

If you do not fully understand these instructions, please ask your doctor to explain them again before you take Revlimid.

Contraception:
In special cases, the doctor may prescribe Revlimid for women who are able to become pregnant. If this is so in your case, it is absolutely essential that you follow the doctor's instructions exactly. The following points are very important:

1. Before the start of the treatment, your doctor will check that you are not pregnant, and he/she will also carry out a pregnancy test every 4 weeks throughout the entire duration of the treatment and 4 weeks during the whole period of the treatment and again 4 weeks after the end of the treatment.
2. Your doctor or another doctor will advise you about appropriate methods of contraception suitable for you. You must generally begin to use a suitable method 4 weeks before the start of the treatment and keep strictly to this not only during the period of the treatment, including periodic interruptions, but also for 4 weeks after the end of the treatment.
3. If you are able to become pregnant, your doctor will record with each prescription that the necessary measures, as outlined above, have been taken and will state that on the relevant *i-SECURE* documents.

If, despite keeping strictly to the methods of contraception, you become pregnant, or you think that you are pregnant, during the treatment with Revlimid or within one month after the end of the treatment, you must tell you doctor immediately. Your doctor will then take the necessary measures.

Male patients who have sexual relations with a woman of childbearing age must use condoms during the period of the treatment, including periodic interruptions, and for 7 days after the end of the treatment. They must also not donate sperm during, and for 7 days after the end of treatment with Revlimid.

Because of the risk to the unborn child, you must never pass on Revlimid to other persons.

You must not donate blood during treatment, during interruptions in treatment or for at least 7 days after stopping treatment.

The marketing authorization holder of Revlimid provides the following materials:

- Information on the problems concerning pregnancy
- A form for you to sign in order to confirm that you have understood the need to prevent a pregnancy while on treatment with Revlimid.

Other precautions

HEMATOLOGIC (BLOOD) TOXICITY. Revlimid can cause significant neutropenia and thrombocytopenia (reduction of blood cells that help fight infection and help the blood to clot).

During the treatment with Revlimid your doctor will carry out regular blood tests, as a reduction in the white blood cell, red blood cell and platelet counts can occur. Such reductions can lead to an increase in infections and bleeding complications. If bleeding occurs and/or patches of bruising appear on your body (e.g. nosebleeds or bruises) or if fever, sore throat, ulcers in the mouth or other signs of an infection appear, you should contact your doctor immediately.

Your doctor will also check your thyroid function before and during the treatment with Revlimid, as your thyroid may become overactive or underactive.

Furthermore, your doctor will carefully perform checks for a tumor flare reaction, which is a temporary increase of the tumour-related symptoms. Due to a tumor flare reaction symptoms like swollen and tender lymph knots, low fever, pain and rash can occur. Fatal cases have also been reported.

Especially in mantel-cell lymphoma patients suffering from a high tumor burden at the beginning of treatment with Revlimid a so called tumorlysis syndrome can appear (including cases resulting in death), caused by the fast lysis of the cancer cells. Consult your doctor if you notice symptoms like nausea, dyspnoea, irregular heartbeat, cloudy urine, fatigue and or joint trouble.

Before and during treatment with lenalidomide, you may be evaluated for signs of cardiopulmonary problems. Therefore, your doctor will possibly check your cardiac function by means of an ECG, especially if you are at the same time using a drug that affects the cardiac function or if you are suffering from a certain heart disorder (QT syndrome). Consult your doctor if you develop chest pain spreading to the arms, neck, jaw, back or stomach, break out in a sweat and become breathless, and feel sick or vomit: these could be symptoms of a heart attack.

If you are taking heart medications with the active ingredient digoxin during your treatment with Revlimid, your doctor will monitor the concentration of digoxin in your blood.

Under the treatment with Revlimid there is an increased risk of the formation of blood clots in the blood vessels, called arterial thrombosis (for example heart attack, stroke) and venous thromboembolic events (for example venous thrombosis, pulmonary embolism). If signs of blood clotting appear, such as pain and/or swelling in a leg or arm, chest pain, sudden respiratory symptoms or coughing, you should contact your doctor immediately. Because of the increased risk of formation of blood clots, hormone replacement therapy after the menopause and treatment with drugs that stimulate the formation of red blood cells (erythropoietin) should not be carried out.

Tell your doctor or healthcare professional immediately if you experience any of the following during or after treatment:
Shortness of breath, fatigue, dizziness, chest pain, faster heartbeat or swelling in the legs or ankles. These may be signs of a serious condition known as pulmonary hypertension.

During the treatment with Revlimid your liver function can be decreased, or the liver can be impaired. Inform your doctor if you suffer from a liver problem in the past or present, if your renal function is impaired or if you take medication especially antibiotics, because these circumstances can increase the risk for liver impairment.

In some cases, patients who underwent transplantation experienced a rejection reaction following the start of treatment with Revlimid. If you receive an organ transplant, your doctor will monitor you for rejection reactions.

Possible severe allergic reactions (called angioedema and anaphylaxis) can occur in the form of hives, rash, swelling of the eyes, mouth or face, shortness of breath or itching. Severe cases of allergic reactions can cause rashes that are locally confined in the beginning but will spread over the whole body leading to large areas of detaching skin (called Steven-Johnson syndrome and/or toxic epidermal necrolysis). In addition to skin reactions, allergic reactions may in very rare cases be accompanied by fever, tiredness, lymph node swelling, an increase in a specific type of white blood cell (eosinophilia) and effects on the liver, kidney or lung (called DRESS). These allergic reactions can be fatal. Tell your doctor immediately if you develop these symptoms.

Because of its inhibitory effect on the immune system, Revlimid can lead to vaccinations being ineffective or to vaccinations with live vaccines causing an infection. Therefore, vaccinations should not be carried out during the treatment with Revlimid.

Revlimid should be used only with caution at the same time as other drugs which affect the immune system. Anticoagulant drugs should only be used after consulting the physician at the same time as Revlimid. You should therefore tell your doctor if you are using any other drugs.

It is important to note that a small number of patients with multiple myeloma or mantel-cell lymphoma may develop additional types of cancer, and it is possible that this risk may be increased with Revlimid treatment. Therefore, your doctor will carefully evaluate the benefit and risk when you are prescribed Revlimid.

If you have multiple myeloma you are susceptible to infections including pneumonia. Treatment with Revlimid in combination with dexamethasone can increase this susceptibility. Your doctor will monitor you for this and advise you to consult him/her immediately if you have signs of an infection, e.g. cough, fever.

Patients with poor general health are more likely to be intolerant of Revlimid combination therapies. For this reason, your doctor will take your age and general health into consideration when carefully assessing whether you will be able to tolerate a combination therapy with Revlimid.

In a small number of patients who had previously been infected with the hepatits B virus, hepatitis B reactivation was observed during treatment with Revlimid. Your doctor will therefore carefully examine you for any signs or symptoms of an active infection with the hepatitis B virus while you are being treated with Revlimid. Inform your doctor if you have been infected with the hepatitis B virus in the past.

Inform your doctor or your pharmacist if you are suffering from other diseases, have any allergies or are taking or applying externally other medicines (including medicines you have bought yourself!).

Pregnancy and Breast feeding

Revlimid must not be taken during pregnancy.

Women of childbearing age should not become pregnant during treatment with Revlimid.

In order to exclude the possibility of a pregnancy, pregnancy tests must be carried out before, during and at the end of the treatment with Revlimid, and effective methods of contraception must be used during and after the end of the treatment.

It is not known whether Revlimid passes into the mother's milk. Therefore, Revlimid should not be administered during breast-feeding, or breast-feeding should be stopped.

Lenalidomide has been shown to pass into human semen. Male patients with a partner of childbearing age must use condoms during and for 7 days after the end of the treatment with Revlimid.

Detailed information concerning contraception is to be found under the heading "When is caution indicated with the use of Revlimid? ".

Driving and using machines

Because of possible side effects such as light-headedness, fatigue or blurred vision, you should take special care when driving motor vehicles or operating machinery.

Important information about some of the ingredients of Revlimid:

Revlimid contains lactose. Therefore, patients with certain rare hereditary disorders of the sugar metabolism (galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption) should not take Revlimid.

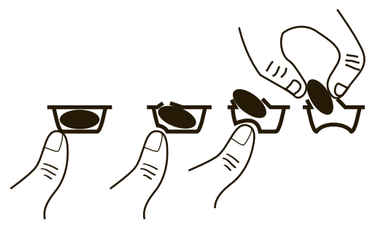
This medicine contains less than 1 mmol sodium (23 mg) per capsule, i.e. it is virtually "sodium-free".

3. How to take or use Revlimid

Always take Revlimid exactly as your doctor has told you. You should check with your doctor or your pharmacist if you are not sure.

Always take the Revlimid capsules at about the same time of day, with or without food, but with some water. The capsules must not be opened or chewed. Wash your hands immediately after they have come into contact with the capsules. Take care not to inhale the powder contained in the capsules (e.g. if a capsule is damaged) and not to allow it to come into contact with the skin or the mucous membranes (eyes!). If it should nevertheless get onto the skin, wash with soap and water, and if it comes into contact with the eyes, rinse out thoroughly with water.

To remove the capsule from the blister, press only one end of the capsule out to push it through the foil. Do not put pressure on the centre of the capsule, as this can cause it to break.



Dosage of Revlimid in combination with bortezomib and dexamethasone in patients with untreated multiple myeloma
The usual dose of Revlimid is 25 mg once daily. There are two different treatment regimens, depending on your doctor's instructions:
a) Take Revlimid for 14 successive days. Then stop taking Revlimid for the next 7 days. A treatment cycle therefore lasts 21 days.
Or
b) Take Revlimid on 21 successive days. Then stop taking Revlimid for the next 7 days. A treatment cycle therefore lasts 28 days.

The dose of bortezomib, the drug that you are taking in combination with Revlimid, will be determined by your doctor depending on your weight and height.

Depending on your doctor's instructions, the dose of dexamethasone, the other drug that you have to take in combination with Revlimid, is 20 mg once daily on days 1, 2, 4, 5, 8, 9, 11 and 12 of a treatment cycle or 40 mg once daily on days 1 to 4 and 9 to 12 of a treatment cycle.

This dosage can be individually adjusted based your doctor's assessment.

The usual dosage regimen is described in the table below:

	Day (of the 21-day cycle)													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15-21
Revlimid (25 mg)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	
Dexamethasone (20 mg)	•	•		•	•			•	•		•	•			

or

	Day (of the 28-day cycle)																						
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22-28
Revlimid (25 mg)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	
Dexamethasone (40 mg)	•	•	•	•					•	•	•	•										

Dosage of Revlimid in multiple myeloma patients after bone marrow transplant
The usual dose of Revlimid is 10 mg once a day. This dose can be increased to 15 mg once a day after assessment by a doctor.

Dosage of Revlimid in combination with dexamethasone in patients with newly diagnosed multiple myeloma
The usual dose of Revlimid is 25 mg once a day. Take Revlimid for 21 consecutive days and then stop the treatment for the next 7 days. One treatment cycle thus lasts for 28 days.

The dosage of dexamethasone, the drug that you have to take in combination with Revlimid, is 40 mg once a day in patients under 75 years and 20 mg once a day in patients over 75 years. Take dexamethasone on days 1,8,15 and 22 of a 28-day treatment cycle. Your doctor may decide to adjust this dosage to your individual needs.

Dosage of Revlimid in combination with melphalan and prednisone in patients with newly diagnosed multiple myeloma
The usual dose of Revlimid is 10 mg once a day. Take Revlimid for 21 consecutive days and then stop the treatment for the next 7 days. One treatment cycle thus lasts for 28 days.
The dosage of melphalan, the drug that you have to take in combination with Revlimid, is 0.18 mg/kg once a day on days 1-4 of 28-day treatment cycle.
The dosage of prednisone the drug that you have to take in combination with Revlimid, is 2 mg/kg once a day on days 1-4 of 28-day treatment cycle.

Dosage of Revlimid in combination with dexamethasone in patients with multiple myeloma who have received at least one other type of treatment before
The usual dose of Revlimid is 25 mg once a day. Take Revlimid for 21 consecutive days and then stop the treatment for the next 7 days. One treatment cycle thus lasts for 28 days.

The dosage of dexamethasone, the drug that you have to take in combination with Revlimid, is 40 mg once a day. The usual dosage regimen is as follows: during the first four 28-day treatment cycles you take dexamethasone on days 1-4, 9-12 and 17-20, and then during the subsequent treatment cycles only on days 1-4. Your doctor may decide to adjust this dosage to your individual needs. Further data on dexamethasone are to be found in the package leaflet for the product concerned.

Your doctor will regularly test your blood during treatment with Revlimid since this treatment may lead to lower levels of white and red blood cells and blood platelets. If a significant decrease in the blood count occurs, your doctor will stop the treatment with Revlimid and will then resume it again at a reduced dosage.

Dosage in myelodysplastic syndrome
The recommended initial dose is 10 mg Revlimid once daily on days 1-21 of the repeating 28-day treatment cycles.

Dosage in mantle cell lymphoma
The recommended initial dose is 25 mg Revlimid once daily on days 1-21 of the repeating 28-day treatment cycles.

Dosage of Revlimid in combination with rituximab in follicular lymphoma
The recommended initial dose is 20 mg Revlimid once daily on days 1-21 of the repeated 28-day treatment cycles. Your doctor will determine the dose of rituximab, which is a medicine given in combination with Revlimid, based on your weight and height.

Your doctor will check your blood regularly while you are taking Revlimid because there may be a decrease in the number of white and red blood cells and platelets. If there is a significant decrease in blood counts, your doctor will stop Revlimid and continue treatment with a reduced dose.

Revlimid is not used in children and adolescents, as no studies have been carried out in these age-groups.

In elderly patients the doctor will carry out the treatment with special care.

In patients with renal function disorders the doctor will carry out the treatment with particular care and will determine the kidney values more frequently.

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

If you have forgotten to take Revlimid and less than 12 hours have elapsed, take the capsule that you have forgotten immediately.

If you have forgotten to take Revlimid and more than 12 hours have elapsed, do not take the capsule you missed. Wait until the next day and take the next capsule at the usual time.

Do not change the dosage prescribed for you on your own initiative. If you think that the effect of the medicine is too weak or too strong, talk to your doctor or your pharmacist.

4. Possible side effects

What side effects can Revlimid have?

Very common: (concerns more than one in 10 users)
Inflammations of the nose and throat region, bronchitis, urinary tract infections, infection of the upper respiratory tract, inflammation of the gastrointestinal tract, pneumonia, inflammation of the nasal mucosa, infection of the paranasal sinuses, influenza, temporary worsening in the symptoms related to the tumor (Tumor-flare), fall in the white and red blood cell and platelet counts, loss of appetite, dehydration, weight loss, changes in laboratory values (potassium, calcium, sodium, blood sugar, liver function tests, enzymes), insomnia, taste disorders, headache, chills, numbness in the extremities, dizziness, blurred vision, fall in blood pressure, cough, shortness of breath, diarrhoea, constipation, nausea, abdominal pain, vomiting, sore or dry mouth, itching, skin eruptions, dry skin, muscle cramps or muscle weakness, back pain, muscle pain, skeletal muscle pain, bone pain, exhaustion, fever, accumulation of fluid in the arms and legs, weakness, depression, cataract, venous thrombosis, digestive problems, joint pain, pains in the limbs, pain in the breast.

Common: (concerns 1 to 10 in 100 users)
Local or systemic infections (caused by bacteria, viruses or fungi, e.g. pneumonia, fungal infection in the mouth), lower respiratory tract infections, lung infection, respiratory tract infections, sepsis, inflammation of the bowel, inflammation of the subcutaneous tissue, disorders of the haematopoietic system (acute myeloid leukaemia), disorders of the bone marrow (myelodysplastic syndrome), tumor lysis syndrome (metabolic complications that may occur during anticancer treatment or even sometimes in the absence of treatment), tumors of the skin, weight gain, iron overload, accumulation of fluid in the tissues, hormonal (cortisone-like) changes (with swelling of the face, accumulation of fat on the trunk), mental confusion, changes of mood, hearing or seeing things that do not exist, mood swings, fear/anxiety, irritability, fatigue, drowsiness, disorders of cerebral blood flow, fainting fits, abnormal sensations in, or weakness of the limbs, trembling, disturbed memory, nerve pain, visual disorders, watering of the eyes, conjunctivitis, rapid or irregular heartbeat, raised blood pressure, bruising, hot flushes, pulmonary embolism, dyspnoea, runny nose, pain in the mouth and throat, nosebleeds, voice disorder, hoarseness, hiccups, upper abdominal pain, flatulence, reddened skin, swelling of the face, discoloration of the skin, sweating, night sweats, loss of hair, impaired liver function, liver damage, reduced renal function, erection difficulties, enlargement of the breasts in men, abnormal periods, falls, chills, neck pain, (acute) renal failure, acute renal damage, non-cardiac breast pain, contusion.

Uncommon: (concerns 1 to 10 in 1,000 users)
Inflammation of the cardiac wall, herpes infection in the eye, shingles, ear infections, disorders of the haematopoietic system (acute T-cell leukaemia), tumours of the nerve tissue, prolonged blood clotting, swelling of lymph nodes, reduced function of the adrenal cortex, thyroid under function, thyroid over function, increased body hair in women, diabetes, emaciation, gout, increased appetite, reduced sexual drive, psychiatric disorders, nervousness, aggression, nightmares, stroke, speech disorders, motor disorders or disorders of balance, impaired concentration, loss of the sense of smell, loss of vision, inflammation of the cornea, irritation or dryness of the eyes, tinnitus, earache, loss of hearing, cardiac insufficiency, slow heartbeat, circulatory collapse, circulatory disorders, increased blood pressure within the blood vessels supplying the lungs (pulmonary arterial hypertension), asthma, blood in the vomit or in the stools (black stools), enteritis, difficulty in swallowing, bleeding of the gums, haemorrhoids, eczema, acne, photosensitivity of the skin, scaling or cracking of the skin, bone disorders, muscle stiffness, swelling of the joints, frequent urination, urinary incontinence, urine retention, thirst, a feeling of cold, rapid swelling of the skin, especially on back of hands or feet, or of eyelids, lips, face, tongue or genitals, viral reactivation (hepatitis B virus, shingles)

Rare (concerns 1 to 10 in 10,000 users)
serious allergic reactions (Anaphylaxis, Steven-Johnson syndrome or toxic epidermal necrolysis), Inflammations of the tissue in the lungs, inflammation of the pancreas, acute graft-versus-host disease.

Very rare: (concerns less than 1 in 10,000 users)
serious allergic reaction (skin rash including eosinophilia and systemic symptoms, called DRESS), brain disorder caused by a virus (called progressive multifocal leukoencephalopathy).

Not known (frequency cannot be estimated on the basis of available data)
Solid organ transplant rejection.

If you notice any side effects, contact your doctor or pharmacist. This also applies in particular to side effects that are not described in this leaflet.

5. How to store Revlimid

What else has to be considered?

Store Revlimid below 30°C, in the original package and out of the reach and sight of children.

Further instructions
The medicine must not be used after the date indicated with "EXP"on the container.

Return any unused or damaged capsules to your doctor or your pharmacist for proper disposal.

Further information may be obtained from your doctor or your pharmacist, who are in possession of the complete data sheet.

6. Further information

What is contained in Revlimid?

Active substance
Lenalidomide: 5 mg, 10 mg, 15 mg or 25 mg

Excipients
Lactose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.
Capsule shell: gelatine, titanium dioxide, iron oxide (only in 10 mg hard capsules), indigocarmine E132 (only in 10 mg and 15 mg hard capsules).
Printing ink: Shellac, propylene glycol, iron oxide, potassium hydroxide.

Where do you obtain Revlimid? What packs are available?

In pharmacies on medical prescription, which may be used only once.
Revlimid 5 mg, 10 mg, 15 mg, and 25 mg: each pack contains 21 hard capsules

To Report Any Side Effect(s):

Saudi Arabia:

The National Pharmacovigilance Centre (NPC)
- Fax: +966-11-205-7662
- SFDA Call Center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa

United Arab Emirates:

Pharmacovigilance and Medical Device Section
P.O. Box: 1853 Dubai UAE Tel: 80011111
Email: pv@mohap.gov.ae
Drug Department Ministry of Health & Prevention Dubai

Oman:

Department of Pharmacovigilance & Drug Information
Directorate General of Pharmaceutical Affairs & Drug Control
Ministry of Health, Sultanate of Oman
Phone Nos. 0096822357687 / 0096822357686
Fax: 0096822358489
Email: pharma-vigil@moh.gov.om
Website: www.moh.gov.om

Iraq:

- Iraqi Pharmacovigilance center, Ministry of Health, Iraq
- Mobile: 00964 7807820490
- Email: iraqiphvc@moh.gov.iq
- Website: www.tec-moh.com

Other Countries:

- Please contact the relevant competent authority.

This is a medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers Union of Arab Pharmacists

Last revision: August 2022

Manufactured by Celgene International Sarl, Boudry, Switzerland

Marketing Authorization Holder: Celgene International Sarl, Boudry, Switzerland
Trademark owner: Celgene Corporation, Summit, USA

Bristol Myers Squibb