Package leaflet: Information for the patient Your doctor may adjust your dose of Lenalidomide or stop your treatment based on the results of your blood tests and on your general condition. If you are newly diagnosed, your doctor may also assess your treatment based on your age and other conditions you already have. Lenalidomide 2.5 mg hard capsules Lenalidomide 5 mg hard capsules You should not donate blood during treatment and for at least 7 days after the end of treatment. Lenalidomide 7.5 mg hard capsules Children and adolescents Lenalidomide 10 mg hard capsules Lenalidomide is not recommended for use in children and adolescents under 18 years. Lenalidomide 15 mg hard capsules Elderly and people with kidney problems Lenalidomide 20 mg hard capsules If you are aged 75 years or older or have moderate to severe kidney problems - your doctor will check you Lenalidomide 25 mg hard capsules carefully before starting treatment. Other medicines and Lenalidomide Read all of this leaflet carefully before you start taking this medicine because it contains important Tell your doctor or nurse if you are taking or have recently taken any other medicines. This is because information for you. Lenalidomide can affect the way some other medicines work. Also, some other medicines can affect the - Keep this leaflet. You may need to read it again. - If you have any further questions, ask your doctor, pharmacist or nurse. In particular, tell your doctor or nurse if you are taking any of the following medicines: - This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if some medicines used to prevent pregnancy such as oral contraceptives, as they may stop working their signs of illness are the same as yours. some medicines used for heart problems – such as digoxin If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects some medicines used to thin the blood – such as warfarin. not listed in this leaflet. See section 4. Pregnancy, breast-feeding and contraception - information for women and men What is in this leaflet Pregnancy 1. What Lenalidomide is and what it is used for For women taking Lenalidomide 2. What you need to know before you take Lenalidomide You must not take Lenalidomide if you are pregnant, as it is expected to be harmful to an unborn baby. 3. How to take Lenalidomide You must not become pregnant while taking Lenalidomide. Therefore you must use effective methods 4. Possible side effects of contraception if you are a woman of childbearing potential (see 'Contraception'). 5. How to store Lenalidomide If you do become pregnant during your treatment with Lenalidomide, you must stop the treatment and 6. Contents of the pack and other information inform your doctor immediately. For men taking Lenalidomide If your partner becomes pregnant whilst you are taking Lenalidomide, you should inform your doctor 1. What Lenalidomide is and what it is used for immediately. It is recommended that your partner seeks medical advice. What Lenalidomide is You must also use effective methods of contraception (see 'Contraception'). Lenalidomide contains the active substance 'lenalidomide'. This medicine belongs to a group of medicines which affect how your immune system works. You must not breast-feed when taking Lenalidomide, as it is not known if lenalidomide passes into breast What Lenalidomide is used for Lenalidomide is used in adults for: - Multiple myeloma Contraception - Myelodysplastic syndromes For women taking Lenalidomide - Mantle cell lymphoma Before starting the treatment, ask your doctor if you are able to become pregnant, even if you think this is - Follicular lymphoma Multiple myeloma If you are able to become pregnant Multiple myeloma is a type of cancer which affects a certain kind of white blood cell, called the plasma you will have pregnancy tests under the supervision of your doctor (before every treatment, at least cell. These cells collect in the bone marrow and divide, becoming out of control. This can damage the every 4 weeks during treatment, and at least 4 weeks after the treatment has finished) except where it has bones and kidneys. been confirmed that the fallopian tubes have been severed and sealed, to stop eggs from reaching the Multiple myeloma generally cannot be cured. However, the signs and symptoms can be greatly reduced uterus (tubal sterilisation) or disappear for a period of time. This is called a 'response'. Newly diagnosed multiple myeloma – in patients who have had a bone marrow transplant you must use effective methods of contraception for at least 4 weeks before starting treatment, during Lenalidomide is used on its own as a maintenance therapy after patients have recovered enough treatment, and until at least 4 weeks after stopping treatment. Your doctor will advise you on following a bone marrow transplant. appropriate methods of contraception. Newly diagnosed multiple myeloma – in patients who cannot have a bone marrow transplant For men taking Lenalidomide Lenalidomide is taken with other medicines. These may include: Lenalidomide passes into human semen. If your female partner is pregnant or able to become pregnant, - a chemotherapy medicine called 'bortezomib' and she does not use effective methods of contraception, you must use condoms during treatment and for at least 7 days after the end of treatment, even if you have had a vasectomy. - an anti-inflammatory medicine called 'dexamethasone' - a chemotherapy medicine called 'melphalan' and Driving and using machines an immunosuppressant medicine called 'prednisone'. Do not drive or operate machines if you feel dizzy, tired, sleepy, have vertigo or blurred vision after You will take these other medicines at the start of treatment and then continue to take Lenalidomide on its taking Lenalidomide If you are aged 75 years or older or have moderate to severe kidney problems - your doctor will check you Lenalidomide contains lactose carefully before starting treatment. Multiple myeloma – in patients who have had treatment before Lenalidomide contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine. Lenalidomide is taken together with an anti-inflammatory medicine called 'dexamethasone'. Lenalidomide can stop the signs and symptoms of multiple myeloma getting worse. It has also been 3. How to take Lenalidomide shown to delay multiple myeloma from coming back following treatment. myeloma, MDS, MCL or FL. Myelodysplastic syndromes (MDS) When Lenalidomide is used to treat multiple myeloma in patients who cannot have a bone marrow MDS are a collection of many different blood and bone marrow diseases. The blood cells become transplant or have had other treatments before, it is taken with other medicines (see section 1 'What abnormal and do not function properly. Patients can experience a variety of signs and symptoms Lenalidomide is used for'). including a low red blood cell count (anaemia), the need for a blood transfusion, and be at risk of When Lenalidomide is used to treat multiple myeloma in patients who have had a bone marrow infection. transplant or to treat patients with MDS or MCL, it is taken alone. Lenalidomide is used alone to treat adult patients who have been diagnosed with MDS, when all of the When Lenalidomide is used to treat follicular lymphoma, it is taken with another medicine called you need regular blood transfusions to treat low levels of red blood cells ('transfusion-dependent 'rituximab'. Always take Lenalidomide exactly as your doctor has told you. Check with your doctor or pharmacist if anaemia') you are not sure. you have an abnormality of cells in the bone marrow called an 'isolated deletion 5q cytogenetic If you are taking Lenalidomide in combination with other medicines, you should refer to the package abnormality'. This means your body does not make enough healthy blood cells leaflets for these medicines for further information on their use and effects. other treatments have been used before, are not suitable or do not work well enough. Treatment cycle Lenalidomide can increase the number of healthy red blood cells that the body produces by reducing the Lenalidomide is taken on certain days over 3 weeks (21 days). number of abnormal cells: this can reduce the number of blood transfusions needed. It is possible that no transfusions will be Every 21 days is called a 'treatment cycle'. needed. Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you do not take any of the medicines. After completing every 21-day cycle, you should start a new 'cycle' over the next 21 days. Mantle cell lymphoma (MCL) MCL is a cancer of part of the immune system (the lymph tissue). It affects a type of white blood cell called 'B-lymphocytes' or B-cells. MCL is a disease where B-cells grow in an uncontrolled way and build Lenalidomide is taken on certain days over 4 weeks (28 days). up in the lymph tissue, bone marrow or blood. Every 28 days is called a 'treatment cycle'. Lenalidomide is used alone to treat adult patients who have previously been treated with other medicines. Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you do not take any of the medicines. After completing every 28-day cycle, you should start a new 'cycle' over the next 28 days. FL is a slow growing cancer that affects the B-lymphocytes. These are a type of white blood cells that help your body fight infection. When you have FL, too many of these B-lymphocytes may collect in your How much Lenalidomide to take blood, bone marrow, lymph nodes and spleen. Before you start treatment, your doctor will tell you: Lenalidomide is taken together with another medicine called 'rituximab' for the treatment of adult how much Lenalidomide you should take patients with previously treated follicular lymphoma. how much of the other medicines you should take in combination with Lenalidomide, if any on what days of your treatment cycle to take each medicine. How Lenalidomide works How and when to take Lenalidomide Lenalidomide works by affecting the body's immune system and directly attacking the cancer. It works in swallow the capsules whole, preferably with water. a number of different ways: do not break, open or chew the capsules. If powder from a broken Lenalidomide capsule makes - by stopping the cancer cells developing contact with the skin, wash the skin immediately and thoroughly with soap and water. - by stopping blood vessels growing in the cancer healthcare professionals, caregivers and family members should wear disposable gloves when by stimulating part of the immune system to attack the cancer cells. handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements 2. What you need to know before you take Lenalidomide Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. You must read the package leaflet of all medicinal products to be taken in combination with Lenalidomide before starting treatment with Lenalidomide. the capsules can be taken either with or without food. you should take Lenalidomide at about the same time on the scheduled days. Do not take Lenalidomide: if you are pregnant, think you may be pregnant or are planning to become pregnant, as Lenalidomide Taking this medicine is expected to be harmful to an unborn child (see section 2, 'Pregnancy, breast-feeding and To remove the capsule from the blister: contraception – information for women and men'). press only one end of the capsule out to push it through the foil if you are able to become pregnant, unless you follow all the necessary measures to prevent you from do not put pressure on the centre of the capsule, as this can cause it to break. becoming pregnant (see section 2, 'Pregnancy, breast-feeding and contraception – information for women and men'). If you are able to become pregnant, your doctor will record with each prescription that the necessary measures have been taken and provide you with this confirmation. if you are allergic to lenalidomide or any of the other ingredients of this medicine listed in section 6. If you think you may be allergic, ask your doctor for advice. If any of these apply to you, do not take Lenalidomide. Talk to your doctor if you are not sure. Warnings and precautions Talk to your doctor, pharmacist or nurse before taking Lenalidomide if: you have had blood clots in the past - you have an increased risk of developing blood clots in the veins <u>Duration of the treatment with Lenalidomide</u> and arteries during treatment Lenalidomide is taken in treatment cycles, each cycle lasting 21 or 28 days (see above 'Treatment cycle'). You should continue the cycles of treatment until your doctor tells you to stop. you have any signs of an infection, such as a cough or fever you have or have ever had previous viral infection, particularly: hepatitis B infection, varicella zoster, HIV. If you are in doubt, talk to your doctor. Treatment with Lenalidomide may cause the virus to If you take more Lenalidomide than you should become active again, in patients who carry the virus. This results in a recurrence of the infection. Your If you take more Lenalidomide than was prescribed, tell your doctor immediately. doctor should check whether you have ever had hepatitis B infection you have kidney problems - your doctor may adjust your dose of Lenalidomide If you forget to take Lenalidomide you have had a heart attack, have ever had a blood clot, or if you smoke, have high blood pressure or If you forget to take Lenalidomide at your regular time and: high cholesterol levels less than 12 hours have passed - take your capsule immediately. you have had an allergic reaction whilst taking thalidomide (another medicine used to treat multiple more than 12 hours have passed - do not take your capsule. Take your next capsule at the usual time the myeloma) such as rash, itching, swelling, dizziness or trouble breathing you have experienced in the past a combination of any of the following symptoms: widespread rash, If you have any further questions on the use of this medicine, ask your doctor or pharmacist. red skin, high body temperature, flu-like symptoms, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes – these are signs of a severe skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity 4. Possible side effects syndrome. (see also section 4 "Possible side effects"). Like all medicines, Lenalidomide can cause side effects, although not everybody gets them. fany of the above apply to you, tell your doctor, pharmacist or nurse before starting treatment. At any time during or after your treatment, tell your doctor or nurse immediately if you: Stop taking Lenalidomide and see a doctor straight away if you notice any of the following serious experience blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change side effects – you may need urgent medical treatment: Hives, rashes, swelling of eyes, mouth or face, difficulty breathing, or itching, which may be of sensation, memory loss or confusion. These may all be symptoms of a serious and potentially fatal $symptoms\ of\ serious\ types\ of\ allergic\ reactions\ called\ angioedema\ and\ anaphylactic\ reaction.$ brain condition known as progressive multifocal leukoencephalopathy (PML). If you had these

A serious allergic reaction that may begin as a rash in one area but spread with extensive loss of skin over the whole body (Stevens-Johnson syndrome and/or toxic epidermal necrolysis).

Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity

Bleeding or bruising in the absence of injury Chest pain or leg pain Shortness of breath

Lenalidomide 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 such as nosebleeds and

Lenalidomide may also cause blood clots in the veins (thrombosis).

you getting AML during your treatment with Lenalidomide. For patients with MCL taking Lenalidomide It is important to note that a small number of patients may develop additional types of cancer, and it is Your doctor will ask you to have a blood test: possible that this risk may be increased with Lenalidomide treatment. Therefore your doctor should

- every week for the first 8 weeks (2 cycles) of treatment then every 2 weeks in cycles 3 and 4 (see section 3 'Treatment cycle' for more information)

For patients with FL taking Lenalidomide

Your doctor will ask you to have a blood test:

Your doctor will ask you to have a blood test:

then at least every month after that.

For patients with MDS taking Lenalidomide

every week for the first 8 weeks of treatment

(see section 4).

blood to clot (platelets).

before treatment

lenalidomide.

- before treatment

Tests and checks

after this it will happen at the start of each cycle and - at least every month.

symptoms prior to treatment with Lenalidomide, tell your doctor about any change in these symptoms.

experience shortness of breath, tiredness, dizziness, pain in the chest, a faster heartbeat, or swelling in

the legs or ankles. These may be symptoms of a serious condition known as pulmonary hypertension

Before and during the treatment with Lenalidomide you will have regular blood tests. This is because

Lenalidomide may cause a fall in the blood cells that help fight infection (white blood cells) and help the

You may be evaluated for signs of cardiopulmonary problems before and during the treatment with

If you have MDS, you may be more likely to get a more advanced condition called acute myeloid leukaemia (AML). In addition, it is not known how Lenalidomide affects the chances of you getting

AML. Your doctor may therefore do tests to check for signs which may better predict the likelihood of

- before treatment every week for the first 3 weeks (1 cycle) of treatment - then every 2 weeks in cycles 2 to 4 (see Section 3 'Treatment cycle' for more information)

- After this it will happen at the start of each cycle and - at least every month.

Your doctor may check if you have a high total amount of tumour throughout the body, including your bone marrow. This could lead to a condition where the tumours break down and cause unusual levels of chemicals in the blood which can lead to kidney failure (this condition is called 'Tumour Lysis

Syndrome'). Your doctor may check you for changes to your skin such as red spots or rashes.

syndrome). See also section 2.

Tell your doctor straight away if you notice any of the following serious side effects:

Fever, chills, sore throat, cough, mouth ulcers or any other symptoms of infection including within the

Bone pain, muscle weakness, confusion or tiredness that might be due to high level of calcium in the

carefully evaluate the benefit and risk when you are prescribed Lenalidomide. **Very common** side effects (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 Muscle cramps, muscle weakness, muscle pain, muscle aches, bone pain, joint pain, back pain, pain in the extremities

- Generalised swelling including swelling of your arms and legs Fever and flu like symptoms including fever, muscle ache, headache, earache, cough and chills Numbness, tingling or burning sensation to the skin, pains in hands or feet, dizziness, tremor Decreased appetite, change in the way things taste

Increase in pain, tumour size or redness around the tumour Constipation, diarrhoea, nausea, vomiting, stomach pain, heartburn

- Low levels of potassium or calcium and/or sodium in the blood

Lenalidomide 7.5 mg hard capsules are capsules size 2 with grey capsule body and green capsule cap, The capsules are provided in packs containing 21 capsules.

Lenalidomide 10 mg hard capsules are capsules size 2 with white capsule body and green capsule cap, The capsules are provided in packs containing 7 or 21 capsules.

Lenalidomide 15 mg hard capsules are capsules size 0 with white capsule body and blue capsule cap,

The capsules are provided in packs containing 7 or 21 capsules.

Lenalidomide 20 mg hard capsules are capsules size 0 with blue capsule body and green capsule cap, vith 22 mm x 8 mm. The capsules are provided in packs containing 21 capsules.

enalidomide 25 mg hard capsules are capsules size 0 with white capsule body and white capsule cap, 24.

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The capsules are provided in packs containing 21 capsules.

- Thyroid functioning less than it should be

the upper respiratory tract

- Clouding of your eye (cataract)

- Abnormal liver test results

- Increase in liver test results

- Increases in your blood sugar levels (diabetes)

- Depression, mood change, difficulty sleeping

- A vague feeling of bodily discomfort, feeling bad

Common side effects (may affect up to 1 in 10 people):

- Destruction of red blood cells (haemolytic anaemia)

by bruising, swelling of skin filled with blood, bruise

- Increased blood pressure, slow, fast or irregular heartbeat

- Increase in a type of protein that indicates inflammation in body

- Skin eruptions, redness of skin, cracking, flaking or peeling skin, hives

Difficulty swallowing, sore throat, difficulty with voice quality or voice changes

or vomiting, which may be symptoms of a heart attack (myocardial infarction)

- Bleeding of the gums, stomach, or bowels

- Decreases in your blood sugar levels

- Shortness of breath

- Blurred vision

function

- Headache

Nosebleed

- Dry skin

- Cough

- Dehydration

- Runny nose

-A fall in blood pressure

- Sore inflamed mouth, dry mouth

- Certain types of skin tumour

- Increase in uric acid in the blood

- Increased sweating, night sweats

- Passing blood in the urine

- Difficulty getting an erection

temporary loss of consciousness

- Muscle weakness, lack of energy

- Bile flow from liver slowed or blocked

- Impaired balance, difficulty moving

- Deafness, ringing in the ears (tinnitus)

- An excess of iron in the body

- Fall which may result in injury

- Bleeding within the skull

- Loss of sex drive (libido)

(called colitis or caecitis)

sometimes death.

inflammation of the pancreas.

tissue in the lungs

Reporting of side effects

5. How to store Lenalidomide

What Lenalidomide contains

The other ingredients are:

brilliant blue FCF (E133).

The other ingredients are:

The other ingredients are:

brilliant blue FCF (E133).

The other ingredients are:

brilliant blue FCF (E133).

The other ingredients are:

The other ingredients are:

nagnesium stearate.

black iron oxide (E172).

The other ingredients are:

capsule shell: gelatin and titanium dioxide (E171).

What Lenalidomide looks like and contents of the pack

The capsules are provided in packs containing 7 or 21 capsules.

The capsules are provided in packs containing 7 or 21 capsules.

nagnesium stearate.

nagnesium stearate.

Store below 30°C.

- Circulatory problems

- Loss of vision

- Low levels of phosphate or magnesium in the blood

Nerve pain, unpleasant abnormal sensation especially to touch

Uncommon side effects (may affect up to 1 in 100 people):

- Damage to the cells of the kidney (called renal tubular necrosis)

- Changes to the colour of your skin, sensitivity to sunlight

with a statin (a type of cholesterol lowering medicines).

Rejection of solid organ transplant (such as kidney, heart).

Keep this medicine out of the sight and reach of children.

The expiry date refers to the last day of that month.

6. Contents of the pack and other information

joints and fever (leukocytoclastic vasculitis).

- Neck pain, chest pain

- Difficulty speaking

- Chills

- Joint swelling

- Liver injury

- Thirst

- Confusion

- Toothache

symptom of blood clots in the lungs, called pulmonary embolism)

- Leg pain (which could be a symptom of thrombosis), chest pain or shortness of breath (which may be a

- Infections of all types, including infection of the sinuses that surround the nose, infection of the lung and

- Kidney problems which include kidneys not working properly or not being able to maintain normal

- Increase in the amount of a substance which results from normal and abnormal breakdown of red blood

- Darkening of your skin, discoloration of your skin resulting from bleeding underneath, typically caused

- Production of much more or much less urine than usual or the inability to control when to urinate

- Stroke, fainting, vertigo (problem with inner ear which leads to feeling that everything is spinning),

- Chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty and breathless, feeling sick

Passing large amounts of urine with bone pain and weakness, which may be symptoms of a kidney

Yellow pigmentation to the skin, mucus membrane or eyes (jaundice), pale coloured stools, dark

coloured urine, skin itch, rash, pain or swelling of the stomach – these may be symptoms of injury to the

- Stomach pain, bloating, or diarrhoea, which may be symptoms of inflammation in the large intestine

- Tumour lysis syndrome - metabolic complications that can occur during treatment of cancer and

sometimes even without treatment. These complications are caused by the break-down products of dying

cancer cells and may include the following: changes to blood chemistry; high potassium, phosphorus,

uric acid, and low calcium consequently leading to changes in kidney function, heart beat, seizures, and

Sudden, or mild but worsening pain in the upper stomach 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

Wheezing, shortness of breath or a dry cough, which may be symptoms caused by inflammation of the

Rare cases of muscle breakdown (muscle pain, weakness or swelling) which can lead to kidney

problems (rhabdomyolysis) have been observed, some of them when lenalidomide is administered

A condition affecting the skin caused by inflammation of small blood vessels, along with pain in the

Breakdown of the wall of the stomach or gut. This may lead to very serious infection. Tell your doctor

if you have severe stomach pain, fever, nausea, vomiting, blood in your stool, or changes in bowel

Viral infections, including herpes zoster (also known as 'shingles', a viral disease that causes a painful

skin rash with blisters) and recurrence of hepatitis B infection (which can cause yellowing of the skin

and eyes, dark brown-colored urine, right-sided stomach pain, fever and feeling nauseous or being

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects

not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Do not use this medicine after the expiry date, which is stated on the blister and on the carton after 'EXP'.

Do not throw away any medicines via wastewater or household waste. Please return unused medicines to

- capsule contents: lactose anhydrous, cellulose, microcrystalline, croscarmellose sodium and

- capsule shell: gelatin, yellow iron oxide (E172), titanium dioxide (E171), black iron oxide (E172) and

capsule contents: lactose anhydrous, cellulose, microcrystalline, croscarmellose sodium and

capsule contents: lactose anhydrous, cellulose, microcrystalline, croscarmellose sodium and

capsule shell: gelatin, titanium dioxide (E171), black iron oxide (E172), yellow iron oxide (E172) and

capsule contents: lactose anhydrous, cellulose, microcrystalline, croscarmellose sodium and

capsule shell: gelatin, titanium dioxide (E171), yellow iron oxide (E172), black iron oxide (E172) and

capsule contents: lactose anhydrous, cellulose, microcrystalline, croscarmellose sodium and

capsule contents: lactose anhydrous, cellulose, microcrystalline, croscarmellose sodium and

capsule shell: gelatin, titanium dioxide (E171), yellow iron oxide (E172), brilliant blue FCF (E133) and

capsule contents: lactose anhydrous, cellulose, microcrystalline, croscarmellose sodium and

Lenalidomide 2.5 mg hard capsules are capsules size 4 with green capsule body and green capsule cap,

Lenalidomide 5 mg hard capsules are capsules size 4 with blue capsule body and blue capsule cap, with

By reporting side effects you can help provide more information on the safety of this medicine.

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

The active substance is lenalidomide. Each capsule contains 2.5 mg of lenalidomide.

The active substance is lenalidomide. Each capsule contains 5 mg of lenalidomide.

capsule shell: gelatin, titanium dioxide (E171) and brilliant blue FCF (E133).

The active substance is lenalidomide. Each capsule contains 7.5 mg of lenalidomide.

The active substance is lenalidomide. Each capsule contains 10 mg of lenalidomide.

The active substance is lenalidomide. Each capsule contains 15 mg of lenalidomide.

- capsule shell: gelatin, titanium dioxide (E171) and brilliant blue FCF (E133).

The active substance is lenalidomide. Each capsule contains 20 mg of lenalidomide.

The active substance is lenalidomide. Each capsule contains 25 mg of lenalidomide.

your pharmacist. These measures will help protect the environment.

- Increase in blood pressure within blood vessels that supply the lungs (pulmonary hypertension).

Not known side effects (frequency cannot be estimated from the available data):

- Shortness of breath especially when lying down (which may be a symptom of heart failure)

- Changes to a protein in the blood that can cause swelling of the arteries (vasculitis)

Manufacturer Tecnimede – Sociedade Técnico-Medicinal S.A. Quinta da Cerca, Caixaria 2565-187 Dois Portos Portugal

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