BIJSLUITER: INFORMATIE VOOR DE GEBRUIKER

Lenalidomide ratiopharm 2,5 mg, harde capsules
Lenalidomide ratiopharm 5 mg, harde capsules
Lenalidomide ratiopharm 7,5 mg, harde capsules
Lenalidomide ratiopharm 10 mg, harde capsules
Lenalidomide ratiopharm 15 mg, harde capsules
Lenalidomide ratiopharm 20 mg, harde capsules
Lenalidomide ratiopharm 25 mg, harde capsules
lenalidomide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What [Product name] is and what it is used for
2. What you need to know before you take [Product name]
3. How to take [Product name]
4. Possible side effects
5. How to store [Product name]
6. Contents of the pack and other information

1. What [Product name] is and what it is used for

What [Product name] is
[Product name] contains the active substance ‘lenalidomide’. This medicine belongs to a group of medicines which affect how your immune system works.

What {Product name] is used for
[Product name] is used in adults for
- Multiple myeloma
- Myelodysplastic syndromes
- Mantle cell lymphoma
- Follicular lymphoma

Multiple myeloma
Multiple myeloma is a type of cancer which affects a certain kind of white blood cell, called the plasma cell. These cells collect in the bone marrow and divide, becoming out of control. This can damage the bones and kidneys.

Multiple myeloma generally cannot be cured. However, the signs and symptoms can be greatly reduced 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
[Product name] is used on its own as a maintenance therapy after patients have recovered enough following a bone marrow transplant.

Newly diagnosed multiple myeloma – in patients who cannot have a bone marrow transplant
[Product name] is taken with other medicines. These may include:
- a chemotherapy medicine called 'bortezomib'
- an anti-inflammatory medicine called 'dexamethasone'
- a chemotherapy medicine called 'melphalan' and
- an immunosuppressant medicine called 'prednisone'.

You will take these other medicines at the start of treatment and then continue to take [Product name] on its own.

If you are aged 75 years or older or have moderate to severe kidney problems - your doctor will check you carefully before starting treatment.

Multiple myeloma – in patients who have had treatment before
[Product name] is taken together with an anti-inflammatory medicine called 'dexamethasone'.

[Product name] can stop the signs and symptoms of multiple myeloma getting worse. It has also been shown to delay multiple myeloma from coming back following treatment.

Myelodysplastic syndromes (MDS)
MDS are a collection of many different blood and bone marrow diseases. The blood cells become abnormal and do not function properly. Patients can experience a variety of signs and symptoms including a low red blood cell count (anaemia), the need for a blood transfusion, and be at risk of infection.

[Product name] is used alone to treat adult patients who have been diagnosed with MDS, when all of the following apply:
- you need regular blood transfusions to treat low levels of red blood cells ('transfusion-dependent anaemia')
- you have an abnormality of cells in the bone marrow called an 'isolated deletion 5q cytogenetic abnormality'. This means your body does not make enough healthy blood cells
- other treatments have been used before, are not suitable or do not work well enough.

[Product name] can increase the number of healthy red blood cells that the body produces by reducing the number of abnormal cells:
- this can reduce the number of blood transfusions needed. It is possible that no transfusions will be needed.

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 up in the lymph tissue, bone marrow or blood.

[Product name] is used alone to treat adult patients who have previously been treated with other medicines.

Follicular lymphoma (FL)
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 blood, bone marrow, lymph nodes and spleen.

[Product name] is taken together with another medicine called 'rituximab' for the treatment of adult patients with previously treated follicular lymphoma.

How [Product name] works
[Product name] works by affecting the body's immune system and directly attacking the cancer. It works in a number of different ways:
- by stopping the cancer cells developing

- by stopping blood vessels growing in the cancer
- by stimulating part of the immune system to attack the cancer cells.

2. What you need to know before you take [Product name]

You must read the package leaflet of all medicinal products to be taken in combination with [Product name] before starting treament with [Product name].

Do not take [Product name]
- if you are pregnant, think you may be pregnant or are planning to become pregnant, **as [Product name] is expected to be harmful to an unborn child** (see section 2, 'Pregnancy, breast-feeding and contraception – information for women and men').
- if you are able to become pregnant, unless you follow all the necessary measures to prevent you from 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 [Product name]. Talk to your doctor if you are not sure.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking [Product name] if
- you have had blood clots in the past - you have an increased risk of developing blood clots in the veins and arteries during treatment.
- 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 [Product name] may cause the virus to become active again in patients who carry the virus. This results in a recurrence of the infection. Your doctor should check whether you have ever had hepatitis B infection.
- you have kidney problems - your doctor may adjust your dose of [Product name].
- you have had a heart attack, have ever had a blood clot, or if you smoke, have high blood pressure or high cholesterol levels.
- you have had an allergic reaction whilst taking thalidomide (another medicine used to treat multiple 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, 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 syndrome (see also section 4 'Possible side effects').

If any 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:
- experience blurred, loss of or double vision, difficulty speaking, weakness in an arm or a leg, a change in the way you walk or problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion. These may all be symptoms of a serious and potentially fatal brain condition known as progressive multifocal leukoencephalopathy (PML). If you had these symptoms prior to treatment with [Product name], 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 (see section 4).

Tests and checks
Before and during the treatment with [Product name] you will have regular blood tests. This is because

[Product name] may cause a fall in the blood cells that help fight infection (white blood cells) and help the blood to clot (platelets).
Your doctor will ask you to have a blood test:
- before treatment
- every week for the first 8 weeks of treatment
- then at least every month after that.

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

For patients with MDS taking [Product name]
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 [Product name] affects the chances of you getting AML. Your doctor may therefore do tests to check for signs which may better predict the likelihood of you getting AML during your treatment with [Product name].

For patients with MCL taking [Product name]
Your doctor will ask you to have a blood test:
- before treatment
- 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)
- after this it will happen at the start of each cycle and
- at least every month.

For patients with FL taking [Product name]
Your doctor will ask you to have a blood test:
- 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.

Your doctor may adjust your dose of [Product name] 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.

Blood donation
You should not donate blood during treatment and for at least 7 days after the end of treatment.

Children and adolescents
[Product name] is not recommended for use in children and adolescents under 18 years.

Elderly and people with kidney problems
If you are aged 75 years or older or have moderate to severe kidney problems - your doctor will check you carefully before starting treatment.

Other medicines and [Product name]
Tell your doctor or nurse if you are taking or have recently taken any other medicines. This is because [Product name] can affect the way some other medicines work. Also, some other medicines can affect the way [Product name] works.

In particular, tell your doctor or nurse if you are taking any of the following medicines:
- some medicines used to prevent pregnancy such as oral contraceptives, as they may stop working
- some medicines used for heart problems – such as digoxin
- some medicines used to thin the blood – such as warfarin

Pregnancy, breast-feeding and contraception - information for women and men

Pregnancy
For women taking [Product name]
- You must not take [Product name] if you are pregnant, as it is expected to be harmful to an unborn baby.
- You must not become pregnant while taking [Product name]. Therefore you must use effective methods of contraception if you are a woman of childbearing potential (see 'Contraception').
- If you do become pregnant during your treatment with [Product name], you must stop the treatment and inform your doctor immediately.

For men taking [Product name]
- If your partner becomes pregnant whilst you are taking [Product name], you should inform your doctor immediately. It is recommended that your partner seeks medical advice.
- You must also use effective methods of contraception (see 'Contraception').

Breast-feeding
You must not breast-feed when taking [Product name], as it is not known if [Product name] passes into breast milk.

Contraception
For women taking [Product name]
Before starting the treatment, 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 every treatment, at least every 4 weeks during treatment, and at least 4 weeks after the treatment has finished) except where it has been confirmed that the fallopian tubes have been severed and sealed, to stop eggs from reaching the uterus (tubal sterilisation)

AND
- you must use effective methods of contraception for at least 4 weeks before starting treatment, during treatment, and until at least 4 weeks after stopping treatment. Your doctor will advise you on appropriate methods of contraception.

For men taking [Product name]
Lenalidomide passes into human semen. If your female partner is pregnant or able to become pregnant, 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. You should not donate semen or sperm during treatment and for at least 7 days after the end of treatment.

Driving and using machines
Do not drive or operate machines if you feel dizzy, tired, sleepy, have vertigo or blurred vision after taking [Product name].

[Product name] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium free'.

3. How to take [Product name]

[Product name] must be given to you by healthcare professionals with experience in treating multiple myeloma, MDS, MCL or FL.

- When [Product name] is used to treat multiple myeloma in patients who cannot have a bone marrow transplant or have had other treatments before, it is taken with other medicines (see section 1 'What [Product name] is used for').
- When [Product name] is used to treat multiple myeloma in patients who have had a bone marrow transplant or to treat patients with MDS or MCL, it is taken alone.
- When [Product name] is used to treat follicular lymphoma, it is taken with another medicine called 'rituximab'.

Always take [Product name] exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you are taking [Product name] in combination with other medicines, you should refer to the package leaflets for these medicines for further information on their use and effects.

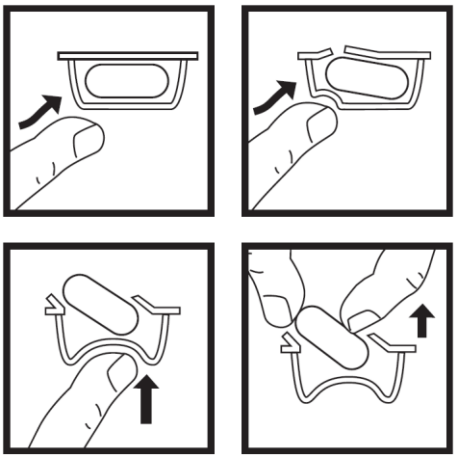
Treatment cycle
[Product name] is taken on certain days over 3 weeks (21 days).
- Every 21 days is called a 'treatment cycle'.
- Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you do not take any of the medicines.
- After completing every 21-day cycle, you should start a new 'cycle' over the next 21 days.

OR
[Product name] is taken on certain days over 4 weeks (28 days).
- Every 28 days is called a 'treatment cycle'.
- 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.

How much [Product name] to take
Before you start treatment, your doctor will tell you:
- how much [Product name] you should take
- how much of the other medicines you should take in combination with [Product name], if any
- on what days of your treatment cycle to take each medicine.

How and when to take [Product name]
- swallow the capsules whole, preferably with water.
- do not break, open or chew the capsules. If powder from a broken [Product name] capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.
- healthcare professionals, caregivers and family members should wear disposable gloves when 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. 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.
- the capsules can be taken either with or without food.
- you should take [Product name] at about the same time on the scheduled days.

Taking this medicine
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.



Duration of the treatment with [Product name]
[Product name] 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.

If you take more [Product name] than you should
If you take more [Product name] than was prescribed, tell your doctor immediately.

If you forget to take [Product name]
If you forget to take [Product name] at your regular time and
- less than 12 hours have passed - take your capsule immediately.
- more than 12 hours have passed - do not take your capsule. Take your next capsule at the usual time the next day.

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

4. Possible side effects

Like all medicines, [Product name] can cause side effects, although not everybody gets them.

Stop taking [Product name] and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:
- Hives, rashes, swelling of eyes, mouth or face, difficulty breathing, or itching, which may be symptoms of serious types of allergic reactions called angioedema and anaphylactic reaction.
- 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 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 bloodstream (sepsis)
- Bleeding or bruising in the absence of injury
- Chest pain or leg pain
- Shortness of breath
- Bone pain, muscle weakness, confusion or tiredness that might be due to high level of calcium in the blood.

[Product name] 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 bruising. [Product name] may also cause blood clots in the veins (thrombosis).

Other side effects
It is important to note that a small number of patients may develop additional types of cancer, and it is possible that this risk may be increased with [Product name] treatment. Therefore your doctor should carefully evaluate the benefit and risk when you are prescribed [Product name].

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
- Rashes, itching
- 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
- Weakness, tiredness
- 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
- Weight loss
- Constipation, diarrhoea, nausea, vomiting, stomach pain, heartburn
- Low levels of potassium or calcium and/or sodium in the blood
- Thyroid functioning less than it should be
- Leg pain (which could be a symptom of thrombosis), chest pain or shortness of breath (which may be a symptom of blood clots in the lungs, called pulmonary embolism)
- Infections of all types, including infection of the sinuses that surround the nose, infection of the lung and the upper respiratory tract
- Shortness of breath
- Blurred vision
- Clouding of your eye (cataract)
- Kidney problems which include kidneys not working properly or not being able to maintain normal function
- Abnormal liver test results
- Increase in liver test results
- Changes to a protein in the blood that can cause swelling of the arteries (vasculitis)
- Increases in your blood sugar levels (diabetes)
- Decreases in your blood sugar levels
- Headache
- Nosebleed
- Dry skin
- Depression, mood change, difficulty sleeping
- Cough
- A fall in blood pressure
- A vague feeling of bodily discomfort, feeling bad
- Sore inflamed mouth, dry mouth
- Dehydration

Common side effects (may affect up to 1 in 10 people):
- Destruction of red blood cells (haemolytic anaemia)
- Certain types of skin tumour
- Bleeding of the gums, stomach, or bowels
- Increased blood pressure, slow, fast or irregular heart beat
- Increase in the amount of a substance which results from normal and abnormal breakdown of red blood cells
- Increase in a type of protein that indicates inflammation in body
- Darkening of your skin, discoloration of your skin resulting from bleeding underneath, typically caused by bruising, swelling of skin filled with blood, bruise
- Increase in uric acid in the blood
- Skin eruptions, redness of skin, cracking, flaking or peeling skin, hives

- Increased sweating, night sweats
- Difficulty swallowing, sore throat, difficulty with voice quality or voice changes
- Runny nose
- Production of much more or much less urine than usual or the inability to control when to urinate
- Passing blood in the urine
- Shortness of breath especially when lying down (which may be a symptom of heart failure)
- Difficulty getting an erection
- Stroke, fainting, vertigo (problem with inner ear which leads to feeling that everything is spinning), temporary loss of consciousness
- 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)
- Muscle weakness, lack of energy
- Neck pain, chest pain
- Chills
- Joint swelling
- Bile flow from liver slowed or blocked
- Low levels of phosphate or magnesium in the blood
- Difficulty speaking
- Liver injury
- Impaired balance, difficulty moving
- Deafness, ringing in the ears (tinnitus)
- Nerve pain, unpleasant abnormal sensation especially to touch
- An excess of iron in the body
- Thirst
- Confusion
- Toothache
- Fall which may result in injury

Uncommon side effects (may affect up to 1 in 100 people):
- Bleeding within the skull
- Circulatory problems
- Loss of vision
- Loss of sex drive (libido)
- Passing large amounts of urine with bone pain and weakness, which may be symptoms of a kidney disorder (Fanconi syndrome)
- 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 liver (hepatic failure)
- Stomach pain, bloating, or diarrhoea, which may be symptoms of inflammation in the large intestine (called colitis or caecitis)
- Damage to the cells of the kidney (called renal tubular necrosis)
- Changes to the colour of your skin, sensitivity to sunlight
- 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 sometimes death.
- 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):
- 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 inflammation of the pancreas.
- Wheezing, shortness of breath or a dry cough, which may be symptoms caused by inflammation of the tissue in the lungs.
- Rare cases of muscle breakdown (muscle pain, weakness or swelling) which can lead to kidney problems (rhabdomyolysis) have been observed, some of them when [Product name] is

administered with a statin (a type of cholesterol lowering medicines).
- A condition affecting the skin caused by inflammation of small blood vessels, along with pain in the joints and fever (leukocytoclastic vasculitis).
- 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 habits.
- 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-coloured urine, right-sided stomach pain, fever and feeling nauseous or being sick).
- Rejection of solid organ transplant (such as kidney, heart).

Reporting of side effects
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 national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Product name]

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

Do not use this medicine after the expiry date which is stated on the blister and on the carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

Do not throw away any medicines via wastewater or household waste. Please return unused medicines to your pharmacist. These measures will help protect the environment.

6. Contents of the pack and other information

What [Product name] contains
- The active substance is lenalidomide. Each capsule contains lenalidomide hydrochloride hydrate corresponding to 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg or 25 mg of lenalidomide.
- The other ingredients are:
  Capsule contents:
  Colloidal anhydrous silica, microcrystalline cellulose, croscarmellose sodium and talc
  Capsule shell:
  [Product name] 2.5 mg: Gelatin, titanium dioxide (E171), yellow iron oxide (E172) and indigo carmine (E132)
  [Product name] 5 mg: Gelatin and titanium dioxide (E171)
  [Product name] 7.5 mg: Gelatin, titanium dioxide (E171) and yellow iron oxide (E172)
  [Product name] 10 mg: Gelatin, titanium dioxide (E171), yellow iron oxide (E172) and indigo carmine (E132)
  [Product name] 15 mg: Gelatin, titanium dioxide (E171) and indigo carmine (E132)
  [Product name] 20 mg: Gelatin, titanium dioxide (E171), yellow iron oxide (E172) and indigo carmine (E132)
  [Product name] 25 mg: Gelatin and titanium dioxide (E171)
  Printing ink:
  Shellac, propylene glycol, black iron oxide (E172), potassium hydroxide and concentrated ammonia solution

What [Product name] looks like and contents of the pack
[Product name] 2.5 mg hard capsules are non-transparent, size "4" (approximately 14.3 mm in length) hard gelatin capsules, imprinted in black with '2.5' on white body and with green cap, containing off-white to pale yellow or beige powder or compressed powder.

[Product name] 5 mg hard capsules are non-transparent, size "4" (approximately 14.3 mm in length) hard gelatin capsules, imprinted in black with '5' on white body and with white cap, containing off-white to pale yellow or beige powder or compressed powder.

[Product name] 7.5 mg hard capsules are non-transparent, size "2" (approximately 18 mm in length) hard gelatin capsules, imprinted in black with '7.5' on white body and with ivory cap, containing off-white to pale yellow or beige powder or compressed powder.

[Product name] 10 mg hard capsules are non-transparent, size "2" (approximately 18 mm in length) hard gelatin capsules, imprinted in black with '10' on ivory body and with green cap, containing off-white to pale yellow or beige powder or compressed powder.

[Product name] 15 mg hard capsules are non-transparent, size "1" (approximately 19.4 mm in length) hard gelatin capsules, imprinted in black with '15' on white body and with blue cap, containing off-white to pale yellow or beige powder or compressed powder.

[Product name] 20 mg hard capsules are non-transparent, size "0" (approximately 21.7 mm in length) hard gelatin capsules, imprinted in black with '20' on blue body and with green cap, containing off-white to pale yellow or beige powder or compressed powder.

[Product name] 25 mg hard capsules are non-transparent, size "0" (approximately 21.7 mm in length) hard gelatin capsules, imprinted in black with '25' on white body and with white cap, containing off-white to pale yellow or beige powder or compressed powder.

Pack sizes:
[Product name] 2.5 mg and 25 mg is available in blister packs containing 21 or 63 hard capsules and in unit-dose blister packs containing 21 x 1 or 63 x 1 hard capsules.

[Product name] 5 mg, 7.5 mg, 10 mg, 15 mg and 20 mg is available in blister packs containing 7, 21 or 63 hard capsules and in unit-dose blister packs containing 7 x 1, 21 x 1 or 63 x 1 hard capsules.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Ratiopharm GmbH
Graf-Arco-Strasse 3
89709 Ulm
Duitsland

Fabrikant
Teva Operations Poland Sp. Z.o.o
ul. Mogilska 80
31-546 Kraków
Polen

Merckle GmbH
Ludwig-Merckle-Strasse 3
89143 Blaubeuren Baden-Wuerttemberg
Duitsland

Pliva Hrvatska d.o.o. (Pliva Croatia Ltd)

Prilaz baruna Filipovića 25
10000 Zagreb
Kroatië

In het register ingeschreven onder:
RVG 121419, harde capsules 2,5 mg
RVG 121433, harde capsules 5 mg
RVG 121434, harde capsules 7,5 mg
RVG 121436, harde capsules 10 mg
RVG 121438, harde capsules 15 mg
RVG 121441, harde capsules 20 mg
RVG 121446, harde capsules 25 mg

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Duitsland	Lenalidomide AbZ 2,5 mg Hartkapseln
	Lenalidomide AbZ 5 mg Hartkapseln
	Lenalidomide AbZ 7,5 mg Hartkapseln
	Lenalidomide AbZ 10 mg Hartkapseln
	Lenalidomide AbZ 15 mg Hartkapseln
	Lenalidomide AbZ 20 mg Hartkapseln
	Lenalidomide AbZ 25 mg Hartkapseln
Nederland	Lenalidomide ratiopharm 2,5 mg, harde capsules
	Lenalidomide ratiopharm 5 mg, harde capsules
	Lenalidomide ratiopharm 7,5 mg, harde capsules
	Lenalidomide ratiopharm 10 mg, harde capsules
	Lenalidomide ratiopharm 15 mg, harde capsules
	Lenalidomide ratiopharm 20 mg, harde capsules
	Lenalidomide ratiopharm 25 mg, harde capsules
Griekenland	Lenalidomide/Teva
Polen	Lenalidomide Teva
Roemenië	Lenalidomidă TEVA 5 mg, capsule
	Lenalidomidă TEVA 10 mg, capsule
	Lenalidomidă TEVA 15 mg, capsule
	Lenalidomidă TEVA 20 mg, capsule

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024