Package leaflet: Information for the patient

Lenalidomide Devatis 2,5 mg, harde capsules
Lenalidomide Devatis 5 mg, harde capsules
Lenalidomide Devatis 7,5 mg, harde capsules
Lenalidomide Devatis 10 mg, harde capsules
Lenalidomide Devatis 15 mg, harde capsules
Lenalidomide Devatis 20 mg, harde capsules
Lenalidomide Devatis 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 Lenalidomide Devatis is and what it is used for

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

What Lenalidomide Devatis is used for
Lenalidomide Devatis is used in adults for:
- Multiple myeloma
- 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
Lenalidomide Devatis 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

Lenalidomide Devatis 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 Lenalidomide Devatis 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
Lenalidomide Devatis is taken together with an anti-inflammatory medicine called 'dexamethasone'.

Lenalidomide Devatis 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.

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.

Lenalidomide Devatis is taken together with another medicine called 'rituximab' for the treatment of adult patients with previously treated follicular lymphoma.

How Lenalidomide Devatis works
Lenalidomide Devatis 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 Lenalidomide Devatis

You must read the package leaflet of all medicinal products to be taken in combination with Lenalidomide Devatis before starting treatment with Lenalidomide Devatis.

Do not take Lenalidomide Devatis:
- if you are pregnant, think you may be pregnant or are planning to become pregnant, **as Lenalidomide Devatis 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 Lenalidomide Devatis. Talk to your doctor if you are not sure.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Lenalidomide Devatis 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 Lenalidomide Devatis 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 Lenalidomide Devatis
- 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 lenalidomide, tell your doctor about any change in these symptoms.

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

<u>For patients with FL taking Lenalidomide Devatis</u>
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 Lenalidomide Devatis 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
Lenalidomide Devatis 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 Lenalidomide Devatis
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This is because Lenalidomide Devatis can affect the way some other medicines work. Also, some other medicines can affect the way Lenalidomide Devatis 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 Lenalidomide Devatis
- You must not take Lenalidomide Devatis if you are pregnant, as it is expected to be harmful to an unborn baby.
- You must not become pregnant while taking Lenalidomide Devatis. 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 Lenalidomide Devatis, you must stop the treatment and inform your doctor immediately.

For men taking Lenalidomide Devatis
- If your partner becomes pregnant whilst you are taking Lenalidomide Devatis, 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 Lenalidomide Devatis, as it is not known if lenalidomide passes into breast milk.

Contraception
For women taking Lenalidomide Devatis
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 Lenalidomide Devatis

Lenalidomide Devatis 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.

Driving and using machines
Do not drive or operate machines if you feel dizzy, tired, sleepy, have vertigo or blurred vision after taking Lenalidomide Devatis.

Lenalidomide Devatis contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsules, that is to say essentially 'sodium-free'.

Lenalidomide Devatis contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Lenalidomide Devatis

Lenalidomide Devatis must be given to you by healthcare professionals with experience in treating multiple myeloma or FL.
- When Lenalidomide Devatis 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 Lenalidomide Devatis is used for').
- When Lenalidomide Devatis is used to treat multiple myeloma in patients who have had a bone marrow transplant, it is taken alone.
- When Lenalidomide Devatis is used to treat follicular lymphoma, it is taken with another medicine called 'rituximab'.

Always take Lenalidomide Devatis exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you are taking Lenalidomide Devatis 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
Lenalidomide Devatis 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
Lenalidomide Devatis 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 Lenalidomide Devatis to take
Before you start treatment, your doctor will tell you:
- how much Lenalidomide Devatis you should take
- how much of the other medicines you should take in combination with Lenalidomide Devatis, if any
- on what days of your treatment cycle to take each medicine.

How and when to take Lenalidomide Devatis

- swallow the capsules whole, preferably with water.
- do not break, open or chew the capsules. If powder from a broken Lenalidomide Devatis 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 Lenalidomide Devatis 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 Lenalidomide Devatis
Lenalidomide Devatis 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 Lenalidomide Devatis than you should
If you take more Lenalidomide Devatis than was prescribed, tell your doctor immediately.

If you forget to take Lenalidomide Devatis
If you forget to take Lenalidomide Devatis 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, this medicine can cause side effects, although not everybody gets them.

Stop taking Lenalidomide Devatis 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.

Lenalidomide Devatis 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.
Lenalidomide Devatis 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 Lenalidomide Devatis treatment. Therefore your doctor should carefully evaluate the benefit and risk when you are prescribed Lenalidomide Devatis.

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, changes 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 level (diabetes)
- Decreases in your blood sugar
- 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 amount 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.

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 Lenalidomide Devatis 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-colored 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 Nederlands Bijwerkingen Centrum Lareb, website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lenalidomide Devatis

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.

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.

Store in the original package. This medicinal product does not require any special temperature storage conditions.

6. Contents of the pack and other information

What Lenalidomide Devatis contains

Lenalidomide Devatis 2.5 mg hard capsules:
- The active substance is lenalidomide. Each capsule contains 2.5 mg of lenalidomide.
- The other ingredients are:
  - *capsule contents:* anhydrous lactose, microcrystalline cellulose (E460 (i)), croscarmellose sodium (E468) and magnesium stearate (E470b)
  - *capsule shell:* gelatine, titanium dioxide (E171), indigo carmine (E132) and yellow iron oxide (E172)

- *printing ink:* shellac, black iron oxide (E172), propylene glycol, potassium hydroxide and concentrated ammonia solution.

Lenalidomide Devatis 5 mg hard capsules:
- The active substance is lenalidomide. Each capsule contains 5 mg of lenalidomide.
- The other ingredients are:
  - *capsule contents:* anhydrous lactose, microcrystalline cellulose (E460 (i)), croscarmellose sodium (E468) and magnesium stearate (E470b)
  - *capsule shell:* gelatine and titanium dioxide (E171)
  - *printing ink:* shellac, black iron oxide (E172), propylene glycol, potassium hydroxide and concentrated ammonia solution.

Lenalidomide Devatis 7.5 mg hard capsules:
- The active substance is lenalidomide. Each capsule contains 7.5 mg of lenalidomide.
- The other ingredients are:
  - *capsule contents:* anhydrous lactose, microcrystalline cellulose (E460 (i)), croscarmellose sodium (E468) and magnesium stearate (E470b)
  - *capsule shell:* gelatine, titanium dioxide (E171) and yellow iron oxide (E172)
  - *printing ink:* shellac, black iron oxide (E172), propylene glycol, potassium hydroxide and concentrated ammonia solution.

Lenalidomide Devatis 10 mg hard capsules:
- The active substance is lenalidomide. Each capsule contains 10 mg of lenalidomide.
- The other ingredients are:
  - *capsule contents:* anhydrous lactose, microcrystalline cellulose (E460 (i)), croscarmellose sodium (E468) and magnesium stearate (E470b)
  - *capsule shell:* gelatine, titanium dioxide (E171), indigo carmine (E132) and yellow iron oxide (E172)
  - *printing ink:* shellac, black iron oxide (E172), propylene glycol, potassium hydroxide and concentrated ammonia solution.

Lenalidomide Devatis 15 mg hard capsules:
- The active substance is lenalidomide. Each capsule contains 15 mg of lenalidomide.
- The other ingredients are:
  - *capsule contents:* anhydrous lactose, microcrystalline cellulose (E460 (i)), croscarmellose sodium (E468) and magnesium stearate (E470b)
  - *capsule shell:* gelatine, titanium dioxide (E171) and indigo carmine (E132)
  - *printing ink:* shellac, black iron oxide (E172), propylene glycol, potassium hydroxide and concentrated ammonia solution.

Lenalidomide Devatis 20 mg hard capsules:
- The active substance is lenalidomide. Each capsule contains 20 mg of lenalidomide.
- The other ingredients are:
  - *capsule contents:* anhydrous lactose, microcrystalline cellulose (E460 (i)), croscarmellose sodium (E468) and magnesium stearate (E470b)
  - *capsule shell:* gelatine, titanium dioxide (E171), indigo carmine (E132) and yellow iron oxide (E172)
  - *printing ink:* shellac, black iron oxide (E172), propylene glycol, potassium hydroxide and concentrated ammonia solution.

Lenalidomide Devatis 25 mg hard capsules:
- The active substance is lenalidomide. Each capsule contains 25 mg of lenalidomide.
- The other ingredients are:
  - *capsule contents:* anhydrous lactose, microcrystalline cellulose (E460 (i)), croscarmellose sodium (E468) and magnesium stearate (E470b)
  - *capsule shell:* gelatine and titanium dioxide (E171)

- *printing ink:* shellac, black iron oxide (E172), propylene glycol, potassium hydroxide and concentrated ammonia solution.

What Lenalidomide Devatis looks like and contents of the pack

Lenalidomide Devatis 2.5 mg hard gelatine capsules consist of a blue-green cap imprinted with "DEVA" and a white body imprinted with "2.5 mg". Both imprints are black. The capsules are filled with white to off-white powder.

Lenalidomide Devatis 5 mg hard gelatine capsules are white imprinted with "DEVA" and "5 mg" in black ink. The capsules are filled with white to off-white powder.

Lenalidomide Devatis 7.5 mg hard gelatine capsules consist of a pale yellow cap imprinted with "DEVA" and a white body imprinted with "7.5 mg". Both imprints are black. The capsules are filled with white to off-white powder.

Lenalidomide Devatis 10 mg hard gelatine capsules consist of a blue-green cap imprinted with "DEVA" and a pale yellow body imprinted with "10 mg". Both imprints are black. The capsules are filled with white to off-white powder.

Lenalidomide Devatis 15 mg hard gelatine capsules consist of a pale blue cap imprinted with "DEVA" and a white body imprinted with "15 mg". Both imprints are black. The capsules are filled with white to off-white powder.

Lenalidomide Devatis 20 mg hard gelatine capsules consist of a blue-green cap imprinted with "DEVA" and a pale blue body imprinted with "20 mg". Both imprints are black. The capsules are filled with white to off-white powder.

Lenalidomide Devatis 25 mg hard gelatine capsules are white imprinted with "DEVA" and "25 mg" in black ink. The capsules are filled with white to off-white powder.

Pack sizes: 7 or 21 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Devatis GmbH
Spitalstrasse 22
79539 Lörrach
Duitsland

In het register ingeschreven onder:
Lenalidomide Devatis 2,5 mg: RVG 125946
Lenalidomide Devatis 5 mg: RVG 125947
Lenalidomide Devatis 7,5 mg: RVG 125948
Lenalidomide Devatis 10 mg: RVG 125949
Lenalidomide Devatis 15 mg: RVG 125950
Lenalidomide Devatis 20 mg: RVG 125951
Lenalidomide Devatis 25 mg: RVG 125952

This medicinal product is authorised in the Member States of the EEA under the following names:

Nederland	Lenalidomide Devatis
Duitsland	Lenalidomid Devatis

This leaflet was last revised in November 2020.