Bijsluiter: Informatie voor de patiënt

Polidma 1 mg, harde capsules
Polidma 2 mg, harde capsules
Polidma 3 mg, harde capsules
Polidma 4 mg, harde capsules
pomalidomide

[Product name] is expected to cause severe birth defects and may lead to the death of an unborn baby.
- Do not take this medicine if you are pregnant or could become pregnant.
- You must follow the contraception advice described in this leaflet.

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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 ‘pomalidomide’. This medicine is related to thalidomide and belongs to a group of medicines which affect the immune system (the body’s natural defences).

What [Product name] is used for
[Product name] is used to treat adults with a type of cancer called ‘multiple myeloma’.

[Product name] is either used with:
- **two other medicines** – called ‘bortezomib’ (a type of chemotherapy medicine) and ‘dexamethasone’ (an anti-inflammatory medicine) in people who have had at least one other treatment - including lenalidomide.

Or
- **one other medicine** – called ‘dexamethasone’ in people whose myeloma has become worse, despite having at least two other treatments - including lenalidomide and bortezomib.

What is multiple myeloma
Multiple myeloma is a type of cancer which affects a certain type of white blood cell (called the ‘plasma cell’). These cells grow out of control and accumulate in the bone marrow. This results in damage to the bones and kidneys.

Multiple myeloma generally cannot be cured. However, treatment can reduce the signs and symptoms of the disease, or make them disappear for a period of time. When this happens, it is called ‘response’.

How [Product name] works
[Product name] works in a number of different ways:
- by stopping the myeloma cells developing
- by stimulating the immune system to attack the cancer cells
- by stopping the formation of blood vessels supplying the cancer cells.

The benefit of using [Product name] with bortezomib and dexamethasone
When [Product name] is used with bortezomib and dexamethasone, in people who have had at least one other treatment, it can stop multiple myeloma getting worse:
- On average, [Product name] when used with bortezomib and dexamethasone stopped multiple myeloma from coming back for up to 11 months - compared with 7 months for those patients who only used bortezomib and dexamethasone.

The benefit of using [Product name] with dexamethasone
When [Product name] is used with dexamethasone, in people who have had at least two other treatments, it can stop multiple myeloma getting worse:
- On average, [Product name] when used with dexamethasone stopped multiple myeloma from coming back for up to 4 months - compared with 2 months for those patients who used only dexamethasone.

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

Do not take [Product name]:
- if you are pregnant or think you may be pregnant or are planning to become pregnant – this is because **[Product name] is expected to be harmful to an unborn child**. (Men and women taking this medicine must read the section "Pregnancy, contraception and breast-feeding – information for women and men" below).
- if you are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see "Pregnancy, contraception and breast-feeding – 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 will provide you with this confirmation.
- if you are allergic to pomalidomide 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 you are uncertain whether any of the conditions above apply to you, talk to your doctor, pharmacist or nurse before taking [Product name].

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking [Product name] if
- you have ever had blood clots in the past. During the treatment with [Product name] you have an increased risk of getting blood clots in your veins and arteries. Your doctor may recommend you take additional treatments (e.g. warfarin) or lower the dose of [Product name] to reduce the chance that you get blood clots.
- you have ever had an allergic reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called 'thalidomide' or 'lenalidomide'.
- you have had a heart attack, have heart failure, have difficulty breathing, or if you smoke, have high blood pressure or high cholesterol levels.
- 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. You may also experience an uneven heartbeat. This condition is called tumour lysis syndrome.
- you have or have had neuropathy (nerve damage causing tingling or pain in your hands or feet).
- you have or have ever had hepatitis B infection. Treatment with [Product name] may cause the hepatitis B virus to become active again in patients who carry the virus, resulting in a recurrence of the infection. Your doctor should check whether you have ever had hepatitis B infection.
- you experience or have experienced in the past a combination of any of the following symptoms: rash on face or extended rash, red skin, high fever, flu-like symptoms, enlarged lymph nodes (signs of severe

skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or drug hypersensitivity syndrome, Toxic Epidermal Necrolysis (TEN) or Stevens-Johnson Syndrome (SJS). See also section 4 “Possible side effects”).

It is important to note that patients with multiple myeloma treated with pomalidomide may develop additional types of cancer, therefore your doctor should carefully evaluate the benefit and risk when you are prescribed this medicine.

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.

At the end of the treatment you should return all unused capsules to the pharmacist.

Pregnancy, contraception and breast-feeding – information for women and men
The following must be followed as stated in the [Product name] Pregnancy Prevention Programme.
Women and men taking [Product name] must not become pregnant or father a child. This is because pomalidomide is expected to harm the unborn baby. You and your partner should use effective methods of contraception while taking this medicine.

Women
Do not take [Product name] if you are pregnant, think you may be pregnant or are planning to become pregnant. This is because this medicine is expected to harm the unborn baby. Before starting the treatment, you should tell your doctor if you are able to become pregnant, even if you think this is unlikely.

If you are able to become pregnant:
- you must use effective methods of contraception for at least 4 weeks before starting treatment, for the whole time you are taking treatment, and until at least 4 weeks after stopping treatment. Talk to your doctor about the best method of contraception for you.
- each time your doctor writes a prescription for you, he will ensure you understand the necessary measures that have to be taken to prevent pregnancy.
- your doctor will arrange pregnancy tests before treatment, at least every 4 weeks during treatment, and at least 4 weeks after the treatment has finished.

If you become pregnant despite the prevention measures:
- you must stop the treatment immediately and talk to your doctor straight away.

Breast-feeding
It is not known if [Product name] passes into human breast milk. Tell your doctor if you are breast-feeding or intend to breast-feed. Your doctor will advise if you should stop or continue breast-feeding.

Men
[Product name] passes into human semen.

- If your partner is pregnant or able to become pregnant, you must use condoms for the whole time you are taking treatment and for 7 days after the end of treatment.
- If your partner becomes pregnant while you are taking [Product name], tell your doctor straight away. Your partner should also tell her doctor straight away.

You should not donate semen or sperm during treatment and for 7 days after the end of treatment.

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

Before and during the treatment with [Product name] you will have regular blood tests. This is because your medicine may cause a fall in the number of blood cells that help fight infection (white cells) and in the number of cells that help to stop bleeding (platelets).

Your doctor should ask you to have a blood test:
- before treatment
- every week for the first 8 weeks of treatment
- at least every month after that for as long as you are taking [Product name].

As a result of these tests, your doctor may change your dose of [Product name] or stop your treatment. The doctor may also change the dose or stop the medicine because of your general health.

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

Other medicines and [Product name]
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take 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, pharmacist or nurse before taking [Product name] if you are taking any of the following medicines:
- some antifungals such as ketaconazole
- some antibiotics (for example ciprofloxacin, enoxacin)
- certain antidepressants such as fluvoxamine.

Driving and using machines
Some people feel tired, dizzy, faint, confused or less alert when taking [Product name]. If this happens to you, do not drive or operate tools or machinery.

[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 a doctor with experience in treating multiple myeloma.

Always take your medicines exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

When to take [Product name] with other medicines

<u>[Product name] with bortezomib and dexamethasone</u>
- See the leaflets that come with bortezomib and dexamethasone for further information on their use and effects.
- [Product name], bortezomib and dexamethasone are taken in 'treatment cycles'. Each cycle lasts 21 days (3 weeks).
- Look at the chart below to see what to take on each day of the 3-week cycle:
  - Each day, look down the chart and find the correct day to see which medicines to take.
  - Some days, you take all 3 medicines, some days just 2 or 1 medicines, and some days none at all.

POM: Pomalidomide; **BOR**: Bortezomib; **DEX**: Dexamethasone

Cycle 1 to 8

	Medicine name		
Day	**POM**	**BOR**	**DEX**
1	√	√	√
2	√		√
3	√		
4	√	√	√
5	√		√
6	√		
7	√		
8	√	√	√
9	√		√
10	√		
11	√	√	√
12	√		√
13	√		
14	√		
15			
16			
17			
18			
19			
20			
21			

Cycle 9 and onwards

	Medicine name		
Day	**POM**	**BOR**	**DEX**
1	√	√	√
2	√		√
3	√		
4	√		
5	√		
6	√		
7	√		
8	√	√	√
9	√		√
10	√		
11	√		
12	√		
13	√		
14	√		
15			
16			
17			
18			
19			
20			
21			

- After completing each 3-week cycle, start a new one.

[Product name] with dexamethasone only
- See the leaflet that comes with dexamethasone for further information on its use and effects.
- [Product name] and dexamethasone are taken in 'treatment cycles'. Each cycle lasts 28 days (4 weeks).
- Look at the chart below to see what to take on each day of the 4-week cycle:
  - Each day, look down the chart and find the correct day to see which medicines to take.
  - Some days, you take both medicines, some days just 1 medicine, and some days none at all.

POM: Pomalidomide; **DEX**: Dexamethasone

	Medicine name	
Day	**POM**	**DEX**
1	√	√
2	√	
3	√	
4	√	
5	√	
6	√	
7	√	
8	√	√
9	√	
10	√	
11	√	
12	√	
13	√	
14	√	
15	√	√
16	√	

	Medicine name	
Day	**POM**	**DEX**
17	√	
18	√	
19	√	
20	√	
21	√	
22		√
23		
24		
25		
26		
27		
28		

- After completing each 4-week cycle, start a new one.

How much [Product name] to take with other medicines

[Product name] with bortezomib and dexamethasone
- The recommended starting dose of [Product name] is 4 mg per day.
- The recommended starting dose of bortezomib will be worked out by your doctor and based on your height and weight (1.3 mg/m^2 body surface area).
- The recommended starting dose of dexamethasone is 20 mg per day. However, if you are over 75, the recommended starting dose is 10 mg per day.

[Product name] with dexamethasone only
- The recommended dose of [Product name] is 4 mg per day.
- The recommended starting dose of dexamethasone is 40 mg per day. However, if you are over 75, the recommended starting dose is 20 mg per day.

Your doctor may need to reduce the dose of [Product name], bortezomib or dexamethasone or stop one or more of these medicines based on the results of your blood tests, your general condition, other medicines you may be taking (e.g. ciprofloxacin, enoxacin and fluvoxamine) and if you experience side effects (especially rash or swelling) from treatment.

If you suffer from liver or kidney problems your doctor will check your condition very carefully whilst you are receiving this medicine.

How to take [Product name]

- Do not break, open or chew the capsules. If powder from a broken 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.
- Swallow the capsules whole, preferably with water.
- You can take the capsules either with or without food.
- Take your capsules at about the same time each day.

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

Your doctor will advise you of how and when to take [Product name] if you have kidney problems and are receiving dialysis treatment.

Duration of the treatment with [Product name]
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 you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take [Product name]
If you forget to take [Product name] on a day when you should, take your next capsule as normal the next day. Do not take a double dose to make up for a forgotten dose.

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.

Serious side effects

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:

- fever, chills, sore throat, cough, mouth ulcers or any other signs of infection (due to less white blood cells, which fight infection).
- bleeding or bruising without a cause, including nosebleeds and bleeding from the bowels or stomach (due to effects on blood cells called 'platelets').
- rapid breathing, rapid pulse, fever and chills, passing very little to no urine, nausea and vomiting, confusion, unconsciousness (due to infection of blood called sepsis or septic shock).
- severe, persistent or bloody diarrhoea (possibly with stomach pain or fever) caused by bacteria called *Clostridium difficile*.
- chest pain, or leg pain and swelling, especially in your lower leg or calves (caused by blood clots).
- shortness of breath (from serious chest infection, inflammation of the lung, heart failure or blood clot).
- swelling of face, lips, tongue and throat, which may cause difficulty breathing (due to serious types of allergic reaction called angioedema and anaphylactic reaction).
- certain types of skin cancer (squamous cell carcinoma and basal cell carcinoma), which can cause changes in the appearance of your skin or growths on your skin. If you notice any changes to your skin whilst taking [Product name], tell your doctor as soon as possible.
- recurrence of hepatitis B infection, which can cause yellowing of the skin and eyes, dark brown-coloured urine, right-sided abdominal pain, fever and feeling nauseous or being sick. Tell your doctor straightaway if you notice any of these symptoms.
- widespread rash, high body temperature, 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, Toxic Epidermal Necrolysis or Stevens-Johnson Syndrome). Stop using

pomalidomide if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

Stop taking [Product name] and see a doctor straight away if you notice any of the serious side effects listed above – you may need urgent medical treatment.

Other side effects
Very common side effects (may affect more than 1 in 10 people):
- shortness of breath (dyspnoea)
- infections of the lungs (pneumonia and bronchitis)
- infections of the nose, sinuses and throat, caused by bacteria or viruses
- flu-like symptoms (influenza)

- low red blood cells, which may cause anaemia leading to tiredness and weakness
- low blood levels of potassium (hypokalaemia), which may cause weakness, muscle cramps, muscle aches, palpitations, tingling or numbness, dyspnoea, mood changes
- high blood levels of sugar
- a fast and irregular heartbeat (atrial fibrillation)

- loss of appetite
- constipation, diarrhoea or nausea
- being sick (vomiting)
- abdominal pain

- lack of energy
- difficulty in falling asleep or staying asleep

- dizziness, tremor
- muscle spasm, muscle weakness
- bone pain, back pain
- numbness, tingling or burning sensation to the skin, pains in hands or feet (peripheral sensory neuropathy)
- swelling of the body, including swelling of the arms or legs
- rashes

- urinary tract infection, which may cause a burning sensation when passing urine, or a need to pass urine more often.

Common side effects (may affect up to 1 in 10 people):
- fall
- bleeding within the skull
- decreased ability to move or feel (sensation) in your hands, arms, feet and legs because of nerve damage (peripheral sensorimotor neuropathy)
- numbness, itching, and a feeling of pins and needles on your skin (paraesthesia)
- a spinning feeling in your head, making it difficult to stand up and move normally

- swelling caused by fluid
- hives (urticaria)
- itchy skin
- shingles

- heart attack (chest pain spreading to the arms, neck, jaw, feeling sweaty and breathless, feeling sick or vomiting)
- chest pain, chest infection
- increased blood pressure

- a fall in the number of red and white blood cells and platelets at the same time (pancytopenia), which will make you more prone to bleeding and bruising. You may feel tired and weak, and short of breath and you are also more likely to get infections
- decreased number of lymphocytes (one type of white blood cells) often caused by infection (lymphopenia)
- low blood levels of magnesium (hypomagnesaemia), which may cause tiredness, generalised weakness, muscle cramps, irritability and may result in low blood levels of calcium (hypocalcaemia), which may cause numbness and, or tingling of hands, feet, or lips, muscle cramps, muscle weakness, light-headedness, confusion
- low blood level of phosphate (hypophosphataemia), which may cause muscle weakness and irritability or confusion
- high blood level of calcium (hypercalcaemia), which may cause slowing reflexes and skeletal muscle weaknesses
- high blood levels of potassium, which may cause abnormal heart rhythm
- Low blood levels of sodium, which may cause tiredness and confusion, muscle twitching, fits (epileptic seizures) or coma
- high blood levels of uric acid, which may cause a form of arthritis called gout
- low blood pressure, which may cause dizziness or fainting

- sore or dry mouth
- changes in the way things taste
- swollen abdomen

- feeling confused
- feeling down (depressed mood)
- loss of consciousness, fainting
- clouding of your eye (cataract)

- damage to the kidney
- inability to pass urine
- abnormal liver test
- pain in the pelvis
- weight loss

Uncommon side effects (may affect up to 1 in 100 people):
- stroke
- inflammation of the liver (hepatitis) which can cause itchy skin, yellowing of the skin and the whites of the eyes (jaundice), pale coloured stools, dark coloured urine and abdominal pain
- the breakdown of cancer cells resulting in the release of toxic compounds into the bloodstream (tumour lysis syndrome). This can result in kidney problems
- underactive thyroid gland, which may cause symptoms such as tiredness, lethargy, muscle weakness, slow heart rate, weight gain

Not known side effects (frequency cannot be estimated from the available data):
- rejection of solid organ transplant (such as heart or liver)

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

This medicine does not require any special storage conditions.

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

Do not throw away any medicines via wastewater or household waste. Any unused medicine should be returned to the pharmacist at the end of treatment. These measures will help protect the environment.

6 Contents of the pack and other information

What [Product name] contains
- The active substance is pomalidomide
- The other ingredients are cellulose microcrystalline (E460), maltodextrin and sodium stearyl fumarate.

[Product name] 1 mg hard capsule:
- Each capsule contains 1 mg of pomalidomide.
- The capsule shell contains: gelatin, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172) and white ink.
- The printing ink contains: shellac glaze, titanium dioxide (E171), propylene glycol.

[Product name] 2 mg hard capsule:
- Each capsule contains 2 mg of pomalidomide.
- The capsule shell contains: gelatin, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172) and white ink.
- The printing ink contains: shellac glaze, titanium dioxide (E171), propylene glycol.

[Product name] 3 mg hard capsule:
- Each capsule contains 3 mg of pomalidomide.
- The capsule shell contains: gelatin, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), indigo carmine aluminium lake (E132) and white ink.
- The printing ink contains: shellac glaze, titanium dioxide (E171), propylene glycol.

[Product name] 4 mg hard capsule:
- Each capsule contains 4 mg of pomalidomide.
- The capsule shell contains: gelatin, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), indigo carmine aluminium lake (E312), erythrosine (E127) and white ink.
- The printing ink contains: shellac glaze, titanium dioxide (E171), propylene glycol.

What [Product name] looks like and contents of the pack

[Product name] 1 mg hard capsules (capsules): Hard gelatin capsule, with a yellow body and red cap, with "PLM 1" printed axial rectified in white in the body.

[Product name] 2 mg hard capsules (capsules): Hard gelatin capsule, with an orange body and red cap, with "PLM 2" printed axial rectified in white in the body.

[Product name] 3 mg hard capsules (capsules): Hard gelatin capsule, with a turquoise body and red cap, with "PLM 3" printed axial rectified in white in the body.

[Product name] 4 mg hard capsules (capsules): Hard gelatin capsule, with a dark blue body and red cap, with "PLM 4" printed axial rectified in white in the body.

Each pack contains 14, 21, 14x1 or 21x1 capsules.
Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Innovis Pharma S.A.
Marathonos Avenue 144
153 51 Pallini Attica
Griekenland

Fabrikant:
Synthon B.V.
Microweg 22
6545 CM Nijmegen
Nederland

Synthon Hispania S.L.
Calle De Castello 1
Sant Boi De Llobregat
08830 Barcelona
Spanje

In het register ingeschreven onder:

Polidma 1 mg, harde capsules	RVG 132108
Polidma 2 mg, harde capsules	RVG 132110
Polidma 3 mg, harde capsules	RVG 132111
Polidma 4 mg, harde capsules	RVG 132113

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

Griekenland	POLIDMA
Nederland	Polidma 1 mg/2 mg/3 mg/4 mg, harde capsules

Deze bijsluiter is voor het laatst goedgekeurd in juni 2024.