POMALYST® CAPSULES

Pomalidomide (1mg, 2mg, 3mg, 4mg)

What is in this leaflet

What POMALYST® is used for

POMALYST® is used to treat adults with a type of cancer called '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'.

POMALYST® 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).

POMALYST® 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.

How POMALYST® works

POMALYST® works in several 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.

<u>The benefit of using POMALYST® with bortezomib and dexamethasone</u>

When POMALYST® 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, POMALYST® 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.

<u>The benefit of using POMALYST® with dexamethasone</u>

When POMALYST® is used with dexamethasone, in people who have had at least two other treatments, it can stop multiple myeloma getting worse:

- On average, POMALYST® 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.

Before you use POMALYST®

- <u>*When you must not use it*</u>
  If you are allergic to pomalidomide or any of the other ingredients of this medicine. 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 POMALYST®

  Pregnancy and lactation
  Women and men taking POMALYST® 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.

  Do not use POMALYST® if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- <u>*Before you start to use it*</u>
  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 POMALYST®, tell your doctor about any change in these symptoms.

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

- <u>*Taking other medicines*</u>
  Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. This is because POMALYST® can affect the way some other medicines work. Also, some other medicines can affect the way POMALYST® works.

How to use POMALYST®

- <u>*How much to use*</u>
  POMALYST® 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. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- <u>*When to use it*</u>
  Use as directed by your doctor or pharmacist.

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- *How long to use it*
  Continue using POMALYST® for as long as your doctor recommends.

- *If you forget to use it*
  Consult your doctor or pharmacist on what you should do if you forget to use it.

  If you forget to take POMALYST® on a day when you should, take your next capsule as normal the next day. Do not increase the number of capsules you take to make up for not taking POMALYST® the previous day.

- *If you use too much (overdose)*
  Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*
  Take your medicine exactly as your doctor has told you.

  Tell all the doctors, dentists and pharmacists treating you that you are taking POMALYST®.

  Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*
  Capsules should not be opened or crushed. If powder from a broken pomalidomide capsule makes contact with the skin, the skin should be washed immediately and thoroughly with soap and water. If pomalidomide is in contact with the mucous membranes, they should be thoroughly flushed with 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.

  Do not stop taking the medicine unless advised by your doctor.

  Do not take any new medicines without consulting your doctor or pharmacist.

  Do not give POMALYST® to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*
  Women
  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 at least one effective method 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 POMALYST® 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
  POMALYST® 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, during dose interruption and for at least 7 days after the end of treatment.
  - If your partner becomes pregnant while you are taking POMALYST®, tell your doctor straight away. Your partner should also tell her doctor straight away. You should not donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days after the end of treatment.

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

  Driving and using machines
  This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, POMALYST® can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Serious side effects:

- Fever, chills, sore throat, cough, mouth ulcers or any other signs of 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, decreased urination, nausea and vomiting, confusion, unconsciousness (due to infection of blood called sepsis or septic shock).
- Severe, persistent or bloody diarrhea (possibly with stomach pain or fever) caused by bacteria called *Clostridium difficile.*

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- 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 a serious type 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.
- 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 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.

***Stop taking POMALYST® and see a doctor straight away** if you notice any of the serious side effects listed above – you may need urgent medical treatment.

Very common:

- Shortness of breath (dyspnoea).
- Infection 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, 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.
- 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:

- 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).
- 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).
- Fall.
- Weight loss.
- Chest pain, chest infection.
- Sore or dry mouth.
- Changes in the way things taste.
- Swollen abdomen.
- Damage to the kidney.
- Inability to pass urine.
- Abnormal liver test.
- Feeling confused.
- Feeling down (depressed mood).
- Loss of consciousness, fainting.
- Clouding of your eye (cataract).
- Pain in the pelvis.
- 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.
- 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.

Uncommon:

- 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,

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lethargy, muscle weakness, slow heart rate, weight gain.

Not known (Frequency cannot be estimated from the available data):

- Rejection of solid organ transplant (such as heart or liver)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of POMALYST®

- *Storage*

  Keep out of the reach and sight of children.

  Store below 30°C.

- *Disposal*

  Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

  Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Unused medicinal product should be returned to the pharmacist at the end of treatment.

Product Description

- *What it looks like*
  - ***POMALYST® 1 mg hard capsule:*** Dark blue opaque cap and yellow opaque body, imprinted "POML" in white ink and "1 mg" in black ink, size 3, hard gelatin capsule.
  - ***POMALYST® 2 mg hard capsule:*** Dark blue opaque cap and orange opaque body, imprinted "POML 2 mg" in white ink, size 1, hard gelatin capsule.
  - ***POMALYST® 3 mg hard capsule:*** Dark blue opaque cap and green opaque body, imprinted "POML 3 mg" in white ink, size 1, hard gelatin capsule.
  - ***POMALYST® 4 mg hard capsule:*** Dark blue opaque cap and blue opaque body, imprinted "POML 4 mg" in white ink, size 1, hard gelatin capsule.

- *Ingredients*
  - Active ingredient: Pomalidomide
  - Inactive ingredients: Mannitol (E421), starch, pregelatinised, sodium stearyl fumarate

- *MAL number(s):*

  POMALYST® Capsules 1mg, 2mg, 3mg, 4mg
  MAL16015077ARZ
  MAL16015078ARZ
  MAL16015079ARZ
  MAL16015080ARZ

Manufacturer

Celgene International Sarl Route de Perreux 1
Boudry 2017
Switzerland

Product Registration Holder

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