PATIENT INFORMATION LEAFLET FOR AMPOMY

SCHEDULING STATUS

S4

AMPOMY 1 mg, hard capsules.

Contains sugar: Sucrose 10,100 mg

AMPOMY 2 mg, hard capsules.

Contains sugar: Sucrose 20,200 mg

AMPOMY 3 mg, hard capsules.

Contains sugar: Sucrose 30,300 mg

AMPOMY 4 mg, hard capsules.

Contains sugar: Sucrose 40,400 mg

Pomalidomide, 1 mg; 2 mg; 3 mg; 4 mg

Read all of this leaflet carefully before you start taking AMPOMY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AMPOMY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WARNING: SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS.

Pomalidomide is structurally related to thalidomide. Thalidomide is a known active substance

that causes severe life-threatening birth defects in humans. Pomalidomide was found to have similar life-threatening birth defects in both rats and rabbits (see 'Do not take AMPOMY" Pregnancy and breastfeeding and fertility'). If Pomalidomide is taken during pregnancy, life-threatening birth defects in humans are expected.

BECAUSE OF THIS TOXICITY AND IN AN EFFORT TO MAKE THE CHANCE OF FOETAL EXPOSURE TO AMPOMY AS NEGLIGIBLE AS POSSIBLE, AMPOMY IS APPROVED FOR MARKETING UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAMME.

UNDER THIS RESTRICTED DISTRIBUTION PROGRAMME, ONLY PRECRIBERS REGISTERED WITH THE PROGRAMME ARE ALLOWED TO PRESCRIBE THE PRODUCT AND PHARMACISTS REGISTERED WITH THE PROGRAMME ARE ALLOWED TO DISPENSE THE PRODUCT. IN ADDITION, PATIENTS MUST BE ADVISED OF, AGREE TO, AND COMPLY WITH THE REQUIREMENTS OF THE RISK MANAGEMENT PROGRAMME.

WARNING: VENOUS THROMBO EMBOLISM:

Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE) occur in patients with multiple myeloma treated with AMPOMY. Consider prophylactic measures after assessing an individual patient's underlying risk factors (see section 4.4).

What is in this leaflet

1. What AMPOMY is and what it is used for

AMPOMY belongs to a group of medicines called immunomodulatory medicines, a group of medicines which affect the immune system (the body's natural defences).

AMPOMY is also used in combination with two other medicines called 'bortezomib' and 'dexamethasone' to treat adult patients with a type of cancer called 'multiple myeloma'. It is used in people who have received at least one previous treatment including a product called 'lenalidomide'.

AMPOMY is used with another medicine called 'dexamethasone' (an anti-inflammatory medicine) to treat adults with a type of cancer called 'multiple myeloma'. It is used in people whose myeloma has become worse, despite having received at least two other kinds of treatment.

2. What you need to know before you take AMPOMY

Do not take AMPOMY:

- If you are pregnant or think you may be pregnant or are planning to become pregnant, as AMPOMY is expected to be harmful to an unborn child (see sections: 'Take special care with AMPOMY' and 'Pregnancy and breastfeeding and fertility').
- If you are able to become pregnant and you are not using or are not able to use effective contraceptive measures to prevent pregnancy (see sections: 'Take special care with AMPOMY' and 'Pregnancy and breastfeeding and fertility') and as outlined in the RISK MANAGEMENT PROGRAMME.
- If you are allergic (hypersensitive) to pomalidomide or any of the other ingredients of AMPOMY listed in the following section: 'What AMPOMY contains'. If you think you may be allergic, ask your doctor for advice.
- If you are a male patient and you are not able to follow or comply with the required contraceptive measures (see sections: 'Take special care with AMPOMY' and 'Pregnancy and breastfeeding and fertility'').

Do not take AMPOMY if any of the above apply to you and talk with your doctor.

Warnings and precautions

Take special care with AMPOMY:

For women taking AMPOMY

Before starting the treatment, you should ask your doctor if you are able to become pregnant, even if you think this is unlikely.

Tell your doctor or health care provider if:

- If you are able to become pregnant
    - you will have pregnancy tests under the supervision of your doctor (before treatment, every 4 weeks during treatment, and 4 weeks after the treatment has finished)
    - you must use two effective methods of contraception for 4 weeks before starting treatment, during treatment including dose interruptions and until 4 weeks after stopping treatment. Your doctor will advise you on appropriate methods of contraception.
- If you become pregnant despite the prevention measures:
    - you must stop the treatment immediately and talk to your doctor straight away

For men taking AMPOMY

AMPOMY passes into human semen.

- If your female partner is pregnant or able to become pregnant, you must use condoms during treatment including dose interruptions and for 4 weeks after the end of treatment (even if you have undergone vasectomy).

Male patients taking AMPOMY should not donate sperm or semen during treatment including dose interruptions and for 4 weeks following the end of treatment.

All patients

- If you have ever had blood clots in the past, during the treatment with AMPOMY 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 AMPOMY to reduce the chance that you get blood clots.

- If 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 may have an increased risk of an allergic reaction to AMPOMY. Talk to your doctor, pharmacist or nurse before taking AMPOMY.
- 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. You may also experience an uneven heartbeat. This condition is called tumour lysis syndrome.
- If you see signs of bleeding, including nose bleeds.
- If you suffer from thyroid conditions (underactive thyroid).
- If you suffer from a heart conditions, or have had previous problems with your heart.
- If you experience any problems with your lung, e.g difficulty in breathing,
- Your doctor will monitor your liver function while you are using AMPOMY.
- There may be an increased risk of infections while you are using AMPOMY. Please notify your doctor if you feel ill or have a fever.

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

Blood donation and blood tests

You should not donate blood during treatment and for 4 weeks after the end of treatment.

Before and during the treatment with AMPOMY 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 AMPOMY.

As a result of these tests, your doctor may change your dose of AMPOMY or stop your treatment.

The doctor may also change the dose or stop the medicine because of your general health.

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

Children and adolescents

Do not give AMPOMY to children younger than 18 years because of insufficient evidence.

Other medicines and AMPOMY

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

AMPOMY may affect how well other medicines work and some medicines can also affect how well AMPOMY works.

It is especially important to mention if you are taking the following:

Tell your doctor if you are taking any of the following medicines:

- some medicines used to treat fungal infections such as ketaconazole;
- certain antidepressants such as fluvoxamine.

AMPOMY with food and drink

The AMPOMY capsules can be taken either with or without food (see following Section: 'How and when to take AMPOMY').

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking AMPOMY

Pregnancy:

Women and men taking AMPOMY must not become pregnant or father a child. This is because AMPOMY (pomalidomide) is expected to harm the unborn baby. You and your partner should use effective methods of contraception while taking AMPOMY.

Do not take AMPOMY 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.

For men taking AMPOMY, please see section: 'Take special care with AMPOMY'. AMPOMY 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 4 weeks after the end of treatment.

You should not donate semen or sperm during treatment and for 4 weeks after the end of treatment.

If your partner becomes pregnant whilst you are taking AMPOMY, you should inform your doctor immediately. It is recommended that your partner seeks medical advice

Breast-feeding

You must not breastfeed you baby while taking AMPOMY.

Driving and using machines

Some people feel tired, dizzy, faint, confused or less alert when taking AMPOMY. If this happens to you, do not drive or operate tools or machinery.

AMPOMY contains sodium

AMPOMY contains less than 1 mmol sodium (1.2 mg) per capsule, i.e. essentially 'sodium-free'.

3. How to take AMPOMY

Do not share medicines prescribed for you with any other person.

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

AMPOMY and the other medicines are taken in treatment cycles.

- Each cycle lasts 28 days (4 weeks).

How much to take:

Your doctor will decide on the dosage is appropriate for you, based on your disease, your body mass and the other medicines that you take with it.

Older patients

No dosage adjustment is required for older patients for AMPOMY. Your doctor will decide if the dosage of the other products need to be adjusted.

After completing each cycle, start a new one.

Your doctor may need to reduce the dose of AMPOMY or dexamethasone or stop the treatment based on the results of your blood tests, your general condition and if you experience side effects

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

Children and adolescents

AMPOMY is not usually used in children and young people under 18 years. Your doctor will decide if it is appropriate to use AMPOMY in younger patients.

Method and route of administration

- Do not break, open or chew the capsules. If powder from a broken AMPOMY capsule makes contact with the skin, wash the skin immediately and thoroughly with soap and water.
- Swallow the capsules whole, preferably with water.
- You can take the capsules either with or without food.
- Take AMPOMY at about the same time each day.

Duration of treatment

You should continue the cycles of treatment until your doctor tells you to stop.

If you take more AMPOMY than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take AMPOMY

If you forget to take AMPOMY 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 AMPOMY the previous day.

If you stop using AMPOMY

Your doctor will decide when to stop treatment with AMPOMY

4. Possible side effects

AMPOMY can have side effects.

Not all side effects reported for AMPOMY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AMPOMY, please consult your health care provider for advice.

If any of the following happens, stop taking AMPOMY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to AMPOMY. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Fever, sore throat, cough, or any other signs of infection (due to reduced number of white blood cells, which fight infection).
- Bleeding or bruising without a cause (due to effects on blood cells called ‘platelets’).
- 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 or blood clot).

Frequent side effects

- 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.
- 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 (hypophosphatemia), 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.

Less frequent side effects

- 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.

Unknown frequent side effects

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

These are all serious side effects. You may need urgent medical attention

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of [PRODUCT NAME].

5. How to store AMPOMY

Store all medicines out of reach of children.

Store at or below 25ºC.

Keep in outer carton until required for use.

Protect from light.

6. Contents of the pack and other information

What AMPOMY 1 mg, 2 mg, 3 mg and 4 mg contains:

The active substances are Pomalidomide.

The other ingredients are:

Cellulose Microcrystalline

Starch Pregelatinized,

Sucrose,

Sodium Stearyl Fumarate

Hard gelatin shell composition for Capsule: Titanium Dioxide & Gelatin

What AMPOMY looks like and contents of the pack

AMPOMY 1 mg,

Opaque, white cap and opaque white body, size '5' hard gelatin capsules imprinted with 'H' on cap and 'P6' on body, filled with pale yellow to yellowish color powder, free from physical defects.

AMPOMY 2 mg,

Opaque, white cap and opaque brown body, size '4' hard gelatin capsules imprinted with 'H' on cap and 'P7' on body, filled with pale yellow to yellowish colour powder, free from physical defects.

AMPOMY 3 mg,

Opaque, white cap and opaque pink body, size '3' hard gelatin capsules imprinted with 'H' on cap and 'P8' on body, filled with pale yellow to yellowish colour powder, free from physical defects.

AMPOMY 4 mg,

Opaque, white cap and opaque white body, size '2' hard gelatin capsules imprinted with 'H' on cap and 'P9' on body, filled with pale yellow to yellowish colour powder, free from physical defects.

AMPOMY 1 mg, 2 mg, 3 mg and 4 mg:

Cold formable laminated film (PVC/Microns Aluminium foil) / plain Aluminium foil (hard tampered) blisters. The blisters are packed in a cardboard carton.

Pack size: 6 x 10's Alu/Alu Blister Pack

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate

Campus, Building No.2,

First Floor, 74 Waterfall Drive, Midrand, 2066

Telephone number: 012 644 1220

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AMPOMY 3 mg: 59/32.16/0311

AMPOMY 4 mg: 59/32.16/0312

Access to the corresponding Professional Information

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate

Campus, Building No.2,

First Floor, 74 Waterfall Drive, Midrand, 2066

Telephone number: 012 644 1220.