Lenmicare Capsules

Lenalidomide (5mg, 10mg, 15mg, 25mg)

What is in this leaflet

What Lenmicare is used for

What is Lenmicare

Lenmicare contains the active substance 'lenalidomide'. This medicine belongs to a group of medicines which affect how your immune system works.

What Lenmicare is used for

Lenmicare is used in adults for multiple myeloma.

What is 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

Lenmicare is used on its own as 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

Lenmicare is taken with an anti-inflammatory medicine called 'dexamethasone'. You will take this other medicine at the start of treatment and then continue to take Lenmicare on its own.

Multiple myeloma - in patients who have had treatment before

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

How Lenmicare works

Lenmicare 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

Lenmicare 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.

Before you use Lenmicare

- *When you must not use it*

Do not take Lenmicare:

- if you are pregnant, think you may be pregnant, or are planning to become pregnant, as **Lenmicare is expected to be harmful to an unborn child** (see below 'Before you start to use it' and 'While you are using it')
- if you are able to become pregnant, unless you follow all the necessary measures to prevent you from becoming pregnant (see below 'Before you start to use it' and 'While you are using it'). 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 other ingredients in this medicine listed in 'Ingredients'. If you think you may be allergic, ask your doctor for advice

If any of these apply to you, do not take Lenmicare. Talk to your doctor if you are not sure.

- *Before you start to use it*

Talk to your doctor or pharmacist before taking Lenmicare.

For women taking Lenmicare

Before starting the treatment, you should 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 at least one 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

You should tell your doctor if you are using implants and levonorgestrel-releasing intra-uterine systems as they are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding.

For men taking Lenmicare

Lenmicare 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 at least 7 days after the end of treatment, even if you have had a vasectomy.

Male patients should not donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days following discontinuation of lenalidomide.

All individuals

Before starting the treatment, you should tell your doctor if you had

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blood clots or taking combined oral contraceptive pills in the past. During treatment with Lenmicare, you have an increased risk of developing blood clots in the blood vessels.

Please also inform your doctor if you have the following conditions: kidney impairment, underactive thyroid, severe skin reaction, liver disorder.

Also tell your doctor or nurse immediately if you experience shortness of breath, tiredness, dizziness, pain in the chest, a faster heartbeat, or swelling in the legs or ankles. These may be symptoms of a serious condition known as pulmonary hypertension.

Before and during the treatment with Lenmicare, you will have regular blood tests as Lenmicare 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

Your doctor may adjust your dose of Lenmicare 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.

Before you start treatment, you should tell your doctor if you have kidney disease. Your doctor may adjust your dose of Lenmicare based on this information.

Please tell your doctor if you have:

- had a heart attack, have ever had a blood clot, or if you smoke, have high blood pressure or high cholesterol levels
- a high total amount of tumour throughout your 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)
- had an allergic reaction whilst taking thalidomide such as rash, itching, swelling, dizziness or trouble breathing
- any signs of an infection, such as a cough or fever
- or have ever had previous viral infection, particularly hepatitis B infection, varicella zona, HIV. If you are in doubt, talk to your doctor. Treatment with Lenmicare may cause 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
- 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))

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.

Children and adolescents
Lenmicare is not recommended for use in children and young people under 18 years.

- *Taking other medicines*

Tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes herbal medicines bought without a prescription. This is because Lenmicare can affect the way some other medicines work. Also, some other medicines can affect the way Lenmicare works.

In particular, tell your doctor or nurse if you are taking any of the following:

- 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

Other medicines not listed above may also interact with Lenmicare. Your doctor or pharmacist have more information on medicines to be careful with or avoid while taking Lenmicare.

How to use Lenmicare

- *How much to use*

Lenmicare must be given to you by healthcare professionals with experience in treating multiple myeloma.

- When Lenmicare 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 dexamethasone
- When Lenmicare is used to treat multiple myeloma in patients who have had a bone marrow transplant, it is taken alone

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

If you are taking Lenmicare in combination with dexamethasone, you should refer to the package leaflet of dexamethasone for further information on its use and effects.

Lenmicare dose
Lenmicare is taken in treatment cycles, each cycle lasting 28 days.

Treatment cycle
Lenmicare is taken on certain days over 4 weeks (28 days).

- Each 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 each 28-day cycle,

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you should start a new 'cycle' over the next 28 days

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

Your doctor may adjust your dose of Lenmicare or stop your treatment based on the results of your blood tests and on your general condition (see 'Before you use Lenmicare').

- *When to use it*
You should swallow the Lenmicare capsules whole, preferably with water. Do not break, open or chew the capsules. If powder from a broken Lenmicare capsule contacts the skin, wash the skin immediately and thoroughly with soap and water. The Lenmicare capsules can be taken either with or without food.

You should take Lenmicare at about the same time on the scheduled days.

- *How long to use it*
Lenmicare is taken in treatment cycles, each cycle lasting 28 days (see above 'Treatment cycle'). You should continue the cycles of treatment until your doctor tells you to stop.

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.

- *If you forget to use it*
If you forget to take Lenmicare at your regular time and:
- less than 12 hours have passed: take your capsule immediately
- more than 12 hours have passed: skip the missed dose, and take your next capsule at the usual time the next day

- *If you use too much (overdose)*
If you take more Lenmicare than was prescribed, tell your doctor immediately. 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*
For women taking Lenmicare
If you do become pregnant during the treatment with Lenmicare, you must stop the treatment and inform your doctor immediately.

For men taking Lenmicare
If your partner becomes pregnant whilst you are taking Lenmicare, you should inform your doctor immediately. It is recommended that your partner seeks medical advice. You must also use effective methods of contraception.

- *Things you must not do*
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.

You must not breast-feed when taking Lenmicare, as it is not known if Lenmicare passes into human milk.

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

- *Things to be careful of*
Do not drive or operate machinery if you feel dizzy, tired, sleepy, have vertigo or blurred vision after taking Lenmicare.

Lenmicare contains lactose. If you have been told by your doctors that you have intolerance to some sugars, contact your doctor before taking Lenmicare.

The doctor should wear disposable gloves when handling blisters or capsules.

Women who are pregnant or suspect pregnancy should not handle blisters or capsules.

Side effects
Like all medicines, Lenmicare can cause side effects, although not everybody gets them.

Serious side effects that are very common (affect more than 1 in 10 people)
Lenmicare 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 (e.g. nosebleeds and bruising). Lenmicare may also cause blood clots in the veins (thrombosis).

Therefore, **you must tell your doctor immediately** if you experience:
- fever and flu-like symptoms including fever, chills, sore throat, muscle ache, headache, cough, mouth ulcers or any other symptoms of infection including within the blood stream (sepsis)
- bleeding or bruising in the absence of injury
- chest pain or leg pain
- shortness of breath

Other side effects are given below
It is important to note that a small number of patients with multiple myeloma may develop additional types of cancer, and it is possible that this risk may be increased with Lenmicare treatment.

Therefore, your doctor should carefully evaluate the benefit and risk when you are prescribed Lenmicare.

Very common side effects (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
- constipation, diarrhoea, nausea, redness of skin, rashes, vomiting, muscle cramps, muscle aches, bone pain, joint

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pain, tiredness, generalised swelling including swelling of the limbs
- fever and flu-like symptoms including fever, muscle ache, headache, earache and chills
- numbness, tingling or burning sensation to the skin, pains in hands or feet, dizziness, tremor, taste disturbance
- 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)
- decreased appetite
- low levels of potassium in the blood
- 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
- infection of the lung and the upper respiratory tract, shortness of breath
- blurred vision
- clouding of your eye (cataract)
- kidney problems
- changes to a protein in the blood that can cause swelling of the arteries (vasculitis)
- increases in your blood sugar level (diabetes)
- headache
- dry skin
- stomach pain
- mood change, difficulty sleeping
- skin rash, runny nose and allergic

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 Lenmicare

Storage

Store below 30°C.
Store in the original package in order to protect from moisture.
Keep the medicine out of reach of children.

Disposal

Do not throw away any medicines via wastewater or household waste. All unused Lenmicare capsules should be returned to the pharmacist. These measures will help protect the environment.

Product Description

- *What it looks like*

Lenmicare capsules 5mg:
A green opaque cap/light brown opaque body, capsule shell size No. 2 imprinted in black ink with "LP" on the cap and "638" on the body and filled with white powder

Lenmicare capsules 10mg:
A yellow opaque cap/gray opaque body, capsule shell size No. 0 imprinted in black ink with "LP" on the cap and "639" on the body and filled with white powder

Lenmicare capsules 15mg:
A brown opaque cap/gray opaque body, capsule shell size No. 2 imprinted in black ink with "LP" on the cap and "640" on the body and filled with white powder

Lenmicare capsules 25mg:
A white opaque cap/white opaque body, capsule shell size No. 0 imprinted in black ink with "LP" on the cap and "642" on the body and filled with white powder

The capsules are packed in outer carton. Each box contains 3 blisters, each blister with 7 capsules.

- *Ingredients*

  - *Active ingredient:*
    Lenalidomide

  - *Inactive ingredients:*
    Capsule contents:
    Lactose anhydrous, microcrystalline cellulose, croscarmellose sodium, magnesium stearate

    Printing ink:
    Shellac, propylene glycol, strong ammonia solution, potassium hydroxide, black iron oxide

    Hard capsule shell:
    (5mg): Gelatin, titanium dioxide, yellow iron oxide, red iron oxide, black iron oxide, FD&C blue #1, FD&C yellow #6
    (10mg): Gelatin, purified water, titanium dioxide, yellow iron oxide, black iron oxide
    (15mg): Gelatin, purified water, titanium dioxide, yellow iron oxide, red iron oxide, black iron oxide
    (25mg): Gelatin, purified water, titanium dioxide

MAL number

MAL22076030AZ (5mg)
MAL25096026AZ (10mg)
MAL25096027AZ (15mg)
MAL22076031AZ (25mg)

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