

APPROVED PATIENT INFORMATION LEAFLET
DR. REDDY'S LABORATORIES (PTY) LTD
KARPILRED
(carfilzomib)
powder for solution for infusion

SCHEDULING STATUS:

S4

KARPILRED powder for solution for infusion**Carfilzomib****Read all of this leaflet carefully before you receiving using KARPILRED**

- 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.
- KARPILRED 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.

What is in this leaflet

1. What KARPILRED is and what it is used for
2. What you need to know before you use KARPILRED
3. How to use KARPILRED
4. Possible side effects
5. How to store KARPILRED
6. Contents of the pack and other information

1. What KARPILRED is and what it is used for

KARPILRED is a medicine that contains the active substance carfilzomib.

KARPILRED is a protease inhibitor. It is a type of medicine used to treat adult patients with multiple myeloma who have received at least one previous treatment for multiple myeloma.

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KARPILRED may be given to you:

- on its own;
- in combination with lenalidomide and dexamethasone;
- in combination with dexamethasone and daratumumab;
- only with dexamethasone.

Lenalidomide, dexamethasone and daratumumab are other medicines used to treat multiple myeloma.

2. What you need to know before you take KARPILRED

Do not receive KARPILRED if you:

- are hypersensitive (allergic) to carfilzomib or any of the ingredients of KARPILRED (See Section 6).
- are pregnant or breastfeeding.

Warnings and precautions

Take special care with KARPILRED

Tell your doctor or healthcare professional before being given the injection if:

- you have heart problems, including a history of chest pain (angina pectoris), heart attack, irregular heartbeat, high blood pressure or if you have ever taken a medicine for your heart.
- you have lung problems, including a history of shortness of breath at rest or with activity (dyspnoea).
- you have high blood pressure.
- you have kidney problems, including kidney failure or if you have ever received dialysis.

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- you have unusual bleeding, including easy bruising, bleeding from an injury, such as a cut that does not stop bleeding in a normal amount of time, or internal bleeding which can indicate you have low platelets.
- you have blood clots in your veins or lungs.
- you have liver problems, including a history of hepatitis, fatty liver, or if you have ever been told your liver is not working properly.
- you have or had seizures.
- you have or had Hepatitis B.
- you have any other major medical disease for which you were hospitalised or received medication.

You may need extra tests to check that your heart, kidneys and liver are working properly.

Other medicines and KARPILRED

Always tell your health care provider if you are taking any other medicines.

(This includes complementary or traditional medicines).

Tell your doctor or nurse if you are taking medicines used to:

- prevent pregnancy such as oral contraceptives or other hormonal contraceptives since these may not be suitable for use with KARPILRED.
- treat heart failure (e.g., digoxin).
- treat gout (e.g., colchicine).

Pregnancy, breastfeeding and fertility

For women receiving KARPILRED

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If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

KARPILRED should not be used if you are trying to become pregnant or are pregnant.

Treatment with KARPILRED has not been evaluated in pregnant women.

While receiving KARPILRED and for 30 days after stopping treatment, you should use a reliable method of birth control to ensure you do not become pregnant. You should talk to your doctor or nurse about reliable methods of birth control.

If you become pregnant while receiving KARPILRED, notify your doctor immediately.

If you are breastfeeding, you should not receive KARPILRED as KARPILRED passes into breast milk in humans. It is important to tell your healthcare professional if you are breastfeeding or plan to do so.

For men receiving KARPILRED

While receiving KARPILRED and for 90 days after stopping treatment, you should use a reliable method of birth control, such as a condom, to ensure your partner does not become pregnant. You should talk to your doctor or nurse about reliable methods of birth control.

If your partner becomes pregnant while you are receiving KARPILRED or within 90 days after stopping treatment, notify your doctor or nurse immediately.

Driving and using machines

Patients being treated with KARPILRED may experience fatigue, dizziness, fainting, and/or a drop in blood pressure. This may impair your ability to drive or operate machinery. If you have these symptoms; you should not drive a car or operate machinery.

It is not always possible to predict to what extent KARPILRED may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which KARPILRED affects them.

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Use in children and adolescents

KARPILRED should not be used in children and adolescents.

Use in elderly

Use KARPILRED with caution in the elderly; they may be more sensitive to its effects.

KARPILRED contains sodium

KARPILRED contains 216 mg sodium (main component of cooking/table salt) in 60 ml vial this is equivalent to 11 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

KARPILRED contains cyclodextrin

KARPILRED contains 3,000 mg cyclodextrin (betadex sulfobutyl ether sodium) per 60 mg vial. This is equivalent to 88 mg/kg for a 70 kg adult.

3. How to receive KARPILRED

You will not be expected to give yourself KARPILRED, it will be given to you by a healthcare professional.

KARPILRED once weekly will be infused into your vein each week for 3 weeks, followed by one week without dosing.

KARPILRED twice weekly will be infused into your vein 2 days in a row, each week for 3 weeks, followed by one week without dosing.

Each 28-day period is considered one treatment cycle.

This means that KARPILRED will be given on Days 1, 8, and 15 for once weekly dosing and Days 1, 2, 8, 9, 15, and 16 for twice weekly dosing of each 28-day cycle.

When KARPILRED is given alone or with lenalidomide and dexamethasone, the doses on Day 8 and 9 of each cycle will not be given from Cycle 13 onwards.

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The dose will be calculated based on your height and weight (body surface area).

Your healthcare professional will determine the dose of KARPILRED that you receive.

Most patients will receive treatment until their disease progresses (gets worse).

However, KARPILRED treatment may also be stopped if you experience side effects that cannot be managed. If you have any further questions on the use of KARPILRED, ask your doctor or nurse.

If you receive more KARPILRED than you should

As KARPILRED is being given by a doctor or nurse, it is unlikely that you will be given too much.

However, if you are given too much KARPILRED your doctor will monitor you for side effects.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

KARPILRED can have side effects.

Not all side effects reported for KARPILRED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving KARPILRED, please consult your doctor, pharmacist or other health care professional for advice.

KARPILRED can make some conditions worse or cause serious side effects, including life-threatening complications.

Tell your doctor immediately if you get any of the following:

- Chest pains, shortness of breath, or if there is swelling of your ankles and feet, which may be symptoms of heart problems.
- Difficulty breathing, including shortness of breath at rest or with activity or a cough (dyspnoea), rapid breathing, feeling like you can't breathe in enough air, wheezing, or cough, which can be signs of lung toxicities.

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- Extremely high blood pressure, severe chest pain, severe headache, confusion, blurred vision, nausea and vomiting, or severe anxiety, which may be signs of a condition known as hypertensive crisis.
- Shortness of breath with everyday activities or at rest, irregular heartbeat, racing pulse, tiredness, dizziness, and fainting spells, which can be signs of a condition known as pulmonary hypertension.
- Swollen ankles, feet, or hands, loss of appetite, passing less urine, or abnormal blood tests, which may be symptoms of kidney problems or kidney failure.
- A side effect called Tumour Lysis Syndrome, which may be caused by the rapid breakdown of tumour cells which results in abnormal blood tests and may cause irregular heartbeat or kidney failure.
- A reaction to KARPILRED infusion, which can include the following symptoms: fever, chills or shaking, joint pain, muscle pain, facial flushing or swelling, swelling of the throat, weakness, shortness of breath, low blood pressure, fainting, slow heartbeat, chest tightness, or chest pain.
- Unusual bruising or bleeding, such as a cut that does not stop bleeding in a normal amount of time or internal bleeding such as coughing up blood, vomiting up blood, dark tarry stools, or bright red blood in your stools.
- Leg pain (which could be a symptom of blood clots in the deep veins of the leg), chest pain or shortness of breath (which may be a symptom of blood clots in the lungs).
- Liver problems, including liver failure, which may cause yellowing of your skin and eyes (jaundice), abdominal pain or swelling, nausea or vomiting. If you have ever had hepatitis B infection, treatment with KARPILRED may cause the hepatitis B infection to become active again.
- Bleeding, bruising, weakness, confusion, fever, nausea, vomiting and diarrhoea, and acute kidney failure, which may be signs of a blood condition known as thrombotic microangiopathy.

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- Headaches, confusion, seizures (fits), visual loss, and high blood pressure (hypertension), which may be symptoms of a neurologic condition known as Posterior Reversible Encephalopathy Syndrome (PRES).
- Blurred or double vision, vision loss, difficulty speaking, weakness in an arm or a leg, a change in the way you walk, problems with your balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion which may be symptoms of a central nervous system infection known as Progressive Multifocal Leukoencephalopathy (PML).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Respiratory tract infection
- Pneumonia
- Inflammation of the nose and throat
- Bronchitis
- Urinary tract infection
- Flu-like symptoms (influenza)
- Shingles
- Runny nose or nasal congestion
- Viral infection
- Sepsis (systemic infection including infection in the blood)
- Low red blood cell count (anaemia) which may cause tiredness (fatigue)
- Low platelets, which may cause easy bruising or bleeding

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- Low white blood cell count, which may decrease your ability to fight infection and may be associated with fever
- Decreased appetite
- Increased blood levels of sugar, calcium, uric acid or potassium
- Decreased blood levels of potassium, calcium, phosphate, magnesium, sodium or protein
- Dehydration
- Difficulty sleeping
- Feeling anxious and confused
- Headache
- Feeling dizzy
- Numbness, tingling or decreased sensation in hands and/or feet
- Reduced sense of touch or sensation
- Blurred vision
- Cataracts (cloudy area in the lens of your eye)
- Ringing in your ears.
- Heart disease including heart attack and heart failure
- Racing pulse
- Irregular heartbeat (palpitations)
- Chest pain
- High or low blood pressure
- Blood clots in the veins (deep vein thrombosis)
- Flushing (when you get red in the face)
- Shortness of breath/difficulty breathing
- Cough
- Nose bleeds

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- Sore mouth and throat
- Wheezing
- Change in voice or hoarseness
- Feeling sick (nausea)
- Runny tummy
- Throwing up (vomiting)
- Hard stools
- Stomach pain
- Indigestion
- Toothache
- Increase in bile
- Rash
- Itchy skin
- Redness of the skin
- Increased sweating
- Back pain
- Muscle spasms
- Joint pain
- Pain in limbs, hands, or feet
- Muscle pain
- Bone pain
- Muscle weakness
- Muscle pain
- Kidney problems
- Fever

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- Swelling of your lower legs or hands
- Tiredness
- Chills
- Pain including chest pain
- Infusion site reaction (pain, redness, irritation, or swelling where you received the injection into your vein)
- Feeling uncomfortable, ill or lack of energy
- Feeling fluish
- Changes in enzymes which are picked up in blood tests
- A type of allergic reaction that develops during or shortly after you receive KARPILRED.

Less frequent side effects:

- Septic shock (life-threatening form of sepsis)
- Inflammation of the colon caused by a bacteria called *Clostridium difficile*
- Reactivation of hepatitis B infection
- Infection of the back of the eye by a virus called the cytomegalovirus
- Thrombotic microangiopathy including Thrombotic Thrombocytopenic Purpura/Haemolytic Uraemic Syndrome (TTP/HUS), which may cause the following symptoms: bleeding, bruising, weakness, confusion, fever, nausea, vomiting, diarrhoea and acute kidney failure
- Allergic reaction
- Tumour lysis syndrome, which may be caused by rapid breakdown of tumour cells and increase the levels of potassium, uric acid, phosphate in your blood, and may lead to acute kidney failure
- Bleeding in the brain
- Stroke

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- Heart attack
- Abnormal amount of fluid between the heart and the lining around the heart (pericardial effusion)
- Swelling and irritation of the lining around the heart (pericarditis)
- Sudden and severe increase in blood pressure
- Bleeding
- Bleeding in the lungs
- Rapid breathing
- Swelling of the throat
- Bleeding in the stomach and bowels
- Intestinal blockage
- Perforation in stomach, small intestine, or large bowel (holes that appear)
- Liver failure
- Reduced or stopped bile flow
- Swelling that is similar to hives, but the swelling is under the skin instead of on the surface
- Multi organ failure.

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

Reporting of side effects

If you get side effects, talk to your doctor, nurse or pharmacist. 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. By reporting side effects, you can help provide more information on the safety of KARPILRED.

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5. How to store KARPILRED

Unopened vials should be stored in a refrigerator (between 2 °C to 8 °C).

Do not freeze.

Keep the vial in the original package to protect it from light.

KARPILRED is for single use only. Return all unused medicine to your pharmacist.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

Do not use KARPILRED after the expiry date printed on the vial and the carton.

Keep all medicines out of reach and sight of children.

6. Contents of the pack and other information

What KARPILRED contains

The active substance is carfilzomib.

The other ingredients are anhydrous citric acid, betadex sulfobutyl ether sodium (sulfobutylether beta-cyclodextrin), sodium hydroxide (for pH adjustment) and water for injection.

What KARPILRED looks like and contents of the pack

KARPILRED is a white to off-white lyophilised cake or powder.

KARPILRED is supplied as a pack size of one sterile vial packed in a carton.

The single-use 50 ml tubular, Type I, clear glass vial with 20 mm neck finish is closed with a grey 20 mm chloro butyl rubber stopper with Fluorotec on plug and a brown flip-off seal.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

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Woodmead

Sandton

Gauteng

2191

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Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website:

<http://www.drreddys.co.za>

For any information about this medicine, please contact the local representative of the Holder of

Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100