

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I receiving Kyprolis?

Kyprolis contains the active ingredient carfilzomib. Kyprolis is used to treat multiple myeloma (cancer of the bone marrow) that has come back after, or not responded to, previous treatment.

For more information, see Section [1. Why am I receiving Kyprolis?](#) in the full CMI.

2. What should I know before I am given Kyprolis?

Do not use if you have ever had an allergic reaction to carfilzomib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Kyprolis?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Kyprolis and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given Kyprolis?

- You will be given Kyprolis as an infusion (slow injection or "drip" into a vein) once- or twice-weekly for 3 weeks followed by 1 week off treatment. Your doctor will decide how long you will receive Kyprolis for.

More instructions can be found in Section [4. How will I be given Kyprolis?](#) in the full CMI.

5. What should I know during treatment with Kyprolis?

| | |
|----------------------------------|--|
| Things you should do | <ul style="list-style-type: none">Remind any doctor, nurse, dentist or pharmacist you visit that you are using KyprolisKeep all your treatment and doctor's appointments so that your progress can be checkedTell your doctor immediately if you become pregnant while taking Kyprolis |
| Things you should not do | <ul style="list-style-type: none">Do not breastfeed during Kyprolis treatment |
| Driving or using machines | <ul style="list-style-type: none">Do not drive or operate machinery or engage in hazardous activities while you are taking Kyprolis if you experience fatigue, dizziness and/or fainting |

For more information, see Section [5. What should I know during treatment with Kyprolis?](#) in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: signs of an allergic reaction, such as rash, difficulty breathing, swelling of face, lips, throat and tongue or other part of the body, rapid pulse or sweating; chest pain, breathing problems.

Very common side effects include: headache, aches or pains in joints or muscles, dizziness, difficulty sleeping, infections in the nasal or throat passages or lung, high blood pressure, breathlessness, cough, diarrhoea/constipation, feeling sick, vomiting, fever, fatigue.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

KYPROLIS®

Active ingredient(s): Carfilzomib (kar-FILZ-oh-mib)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Kyprolis. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Kyprolis.**

Where to find information in this leaflet:

- [1. Why am I receiving Kyprolis?](#)
- [2. What should I know before I am given Kyprolis?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Kyprolis?](#)
- [5. What should I know during treatment with Kyprolis?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I receiving Kyprolis?

Kyprolis contains the active ingredient carfilzomib. Kyprolis is an anti-cancer medicine used to treat multiple myeloma (cancer of the bone marrow) that has come back after or not responded to previous treatment.

Kyprolis will be given to you in combination with other medicines that are also used to treat multiple myeloma.

2. What should I know before I am given Kyprolis?

Warnings

Do not use Kyprolis if you are allergic to:

- Any medicine containing carfilzomib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- Have allergies to any other medicines, foods, preservatives or dyes.
- Have or have had any other medical conditions including:
 - heart problems, including a history of chest pain (angina), heart attack, irregular heartbeat, high blood pressure, or if you have ever taken a medicine for your heart
 - lung problems, including a history of shortness of breath at rest or with activity
 - kidney problems, including kidney failure or if you have ever received dialysis
 - liver problems, including a history of hepatitis, fatty liver or if you have ever been told your liver is not working properly
 - bleeding or bruising more easily than normal
 - blood clots in your veins and small blood vessels
 - any other major disease for which you were hospitalised or received medication.
- Take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under [Section 6. Are there any side effects?](#)

Pregnancy

Check with your doctor if you are pregnant or intend to become pregnant. Kyprolis is not recommended to be used during pregnancy. Women receiving Kyprolis must use a reliable method of birth control during and for 1 month after receiving Kyprolis. Men receiving Kyprolis must use a reliable method of birth control during and for 3 months after receiving Kyprolis.

Tell your doctor immediately if you become pregnant while using Kyprolis, or within 1 month of stopping treatment with Kyprolis or, if you are a man receiving Kyprolis, if your partner becomes pregnant whilst you are using Kyprolis or within 3 months of you stopping treatment with Kyprolis.

Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed. Kyprolis is not recommended for use if you are breastfeeding. It is not known if the active ingredient in Kyprolis passes into breast milk. A decision on whether to discontinue breastfeeding or discontinue therapy with Kyprolis should be made.

Your doctor can discuss the risks and benefits with you.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking medicines used to prevent pregnancy, including oral and hormonal contraceptives.

Read the CMI leaflets of all medicines you take in combination with Kyprolis. This will help you understand the information related to those medicines.

Some medicines may interfere with Kyprolis and affect how it works. You may need to use different amounts of your medicines or take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Kyprolis.

4. How will I be given Kyprolis?

When you will be given Kyprolis

You will be given Kyprolis either once weekly or twice weekly by a healthcare professional. Your doctor will decide which regimen is best suited for you. One treatment cycle lasts 28 days.

- Kyprolis once weekly is given each week for 3 weeks, followed by a 1-week break. Kyprolis is usually given on days 1, 8 and 15.

- Kyprolis twice weekly is given 2 days in a row, each week for 3 weeks, followed by a 1-week break. Kyprolis is usually given on days 1, 2, 8, 9, 15 and 16.

How much Kyprolis will you be given

Your doctor will determine the dose of Kyprolis you receive which will be calculated based on your height and weight (body surface area).

How is Kyprolis given

Kyprolis is dissolved in sterile water for injections and the solution is given as an infusion into your vein; this is called an intravenous (IV) infusion. Treatment with Kyprolis will be under the supervision of a doctor, and your treatment will be given to you by a doctor or nurse.

How long to take Kyprolis

Your doctor will decide how long you will take Kyprolis. This will depend on how well you respond to treatment.

If you are given too much Kyprolis

Kyprolis will be given to you by your doctor or nurse, your doctor will treat and monitor your side effects.

5. What should I know during treatment with Kyprolis?

Things you should do

Keep all your doctor's appointments so that your progress can be checked. Your doctor may do blood tests to check on your progress and detect any unwanted side effects.

Tell your doctor immediately if you become pregnant while taking Kyprolis.

Remind any doctor, nurse, dentist or pharmacist you visit that you are using Kyprolis.

Call your doctor straight away if you have:

- Chest pain, shortness of breath, or if there is swelling of your ankles and feet, shortness of breath with everyday activities or at rest, irregular heartbeat, racing pulse, tiredness, dizziness, and fainting spells which may be symptoms of heart problems
- Difficulty breathing, including shortness of breath at rest or with activity or a cough, rapid breathing, wheezing, or cough.
- Severe chest pain, severe headache, confusion, blurred vision, nausea and vomiting, or severe anxiety
- 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 reaction at any time during your infusion, symptoms may include fever, chills or shaking, joint pain, muscle pain, facial flushing or swelling, weakness, shortness of breath, fainting, chest tightness or 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, chest pain or shortness of breath (which may be a symptom of blood clots)
- Yellowing of your skin and eyes, abdominal pain or swelling, nausea or vomiting.

- Headaches, confusion, seizures, visual loss, and high blood pressure,
- Blurred or double vision, vision loss, difficulty speaking, weakness in an arm or leg, a change in the way you walk, problems with your balance, persistent numbness, decreased or loss of sensation, memory loss or confusion.

Things you should not do

- Do not breastfeed during Kyprolis treatment
- Do not miss your appointment. Keep all of your doctor's appointments so that your progress can be checked.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Kyprolis affects you.

Kyprolis may cause fatigue, dizziness and/or fainting in some people. If you have any of these symptoms, do not drive or operate machinery or engage in hazardous activities.

Looking after your medicine

Kyprolis will be prepared for your infusion by your health care team.

Getting rid of any unwanted medicine

Your doctor or nurse will dispose of this medicine.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <p>General:</p> <ul style="list-style-type: none"> • Difficulty sleeping • General feeling of illness or discomfort • Toothache • Swelling of the throat <p>Heart:</p> <ul style="list-style-type: none"> • Rapid, pounding or fluttering heartbeat • Chest discomfort or pressure <p>Eyes and ears:</p> <ul style="list-style-type: none"> • Difficulty seeing or blurred vision • Persistent noise in the ears (ringing, buzzing, whistling) <p>Nervous system:</p> <ul style="list-style-type: none"> • Dizziness, light-headedness and fainting <p>Mood-related:</p> <ul style="list-style-type: none"> • Difficulty sleeping (insomnia) • Anxiety <p>Gut and digestion:</p> <ul style="list-style-type: none"> • Difficulty swallowing | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> Abdominal pain, cramping and tenderness Constipation Decreased appetite Dehydration Persistent diarrhoea (for more than 2 days) Indigestion Bloated abdomen Mild to severe nausea or vomiting <p>Lung (Lungs and upper airways):</p> <ul style="list-style-type: none"> Change in voice or hoarseness Breathless (with exertion or at rest) Cough whilst lying down Cough with or without phlegm Nosebleed Shortness of breath Wheezing, difficulty breathing, rapid breathing <p>Skin:</p> <ul style="list-style-type: none"> Increased sweating Rash, redness of the skin or itchy skin | |

| Less serious side effects | What to do |
|---|---|
| <p>Infection:</p> <ul style="list-style-type: none"> High temperature or chills Runny or blocked nose, sneezing, facial pressure or pain Sore throat, inflammation of the nose and throat Pain during urination or urgency to urinate Viral infection <p>Muscle and skeleton:</p> <ul style="list-style-type: none"> Back pain, pain in limbs, bone, hands or feet Muscle weakness or spasms | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side-effects

| Serious side effects | What to do |
|---|--|
| <p>Signs of heart problems or heart failure:</p> <ul style="list-style-type: none"> Sudden or sharp chest pain, tightness or discomfort that becomes worse with deep breathing or coughing Rapid, strong, or irregular heartbeat Fainting spells <p>Allergic reaction:</p> <ul style="list-style-type: none"> Skin rash, itching or hives on the skin Shortness of breath, wheezing or difficulty breathing Swelling of the face, lips, tongue, throat or other parts of the body | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> Rapid pulse or sweating <p>Signs of liver problems:</p> <ul style="list-style-type: none"> Pain under the right ribcage (in the liver) Yellowing of the skin and/or whites of the eyes, possibly with brown or orange urine Abdominal pain or swelling Loss of appetite, nausea or vomiting <p>Signs of nervous system problems:</p> <ul style="list-style-type: none"> Headache Dizziness Slurred or loss of speech Numbness, tingling or weakness of the hands and/or feet Confusion, seizures, visual loss Altered consciousness | |

Serious side-effects

| Serious side effects | What to do |
|---|--|
| <p>Signs of lung problems:</p> <ul style="list-style-type: none"> Severe breathlessness Cough, wheezing, phlegm, occasionally with blood Pain or swelling in the throat <p>Signs of blood problems:</p> <ul style="list-style-type: none"> Tiredness and fatigue Bruising or bleeding easily Fever or infections Weakness, confusion, nausea, vomiting, diarrhoea Leg pain (which could be a symptom of blood clots) <p>Signs of gut problems:</p> <ul style="list-style-type: none"> Diarrhoea or constipation, including watery diarrhoea 10-15 times/day with abdominal cramping and pain, rapid heart rate, fever, nausea and dehydration Nausea and/or vomiting Severe stomach pain Coffee grounds or black sticky bowel motions (stools) or bright red blood in bowel motions Coughing or vomiting up blood <p>General:</p> <ul style="list-style-type: none"> Infusion reaction, including at the site of infusion (pain, redness, irritation or swelling where you received the injection into your vein) Pain, swelling and tenderness in a limb, usually the calf Drowsiness; cold, clammy and pale or mottled skin | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

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| Serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none">• Pain behind breast bone, sometimes spreading to neck and shoulders, and sometimes fever <p>Signs of muscle problems:</p> <ul style="list-style-type: none">• Severe muscle pain; pain in joint or muscle, muscle ache• Muscle weakness <p>Signs of eye problems:</p> <ul style="list-style-type: none">• Visual loss or disturbance <p>Signs of kidney problems:</p> <ul style="list-style-type: none">• Swollen ankles, feet, or hands• Passing less or no urine | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Kyprolis contains

| | |
|---|--|
| Active ingredient (main ingredient) | Carfilzomib |
| Other ingredients (inactive ingredients) | Sulfobutyl betadex sodium Citric acid Sodium hydroxide |

Do not take this medicine if you are allergic to any of these ingredients.

What Kyprolis looks like

Kyprolis is supplied as a white-to-off-white powder in a glass vial.

Each pack contains one single-use vial.

60 mg carfilzomib in Kyprolis 60 mg vial (Aust R 283228).

30 mg carfilzomib in Kyprolis 30 mg vial (Aust R 266773).

10 mg carfilzomib in Kyprolis 10 mg vial (Aust R 288527).

Who distributes Kyprolis?

Amgen Australia Pty Ltd.,
Level 11, 10 Carrington Street
Sydney NSW 2000.

Ph: 1800 803 638

www.amgenmedinfo.com.au