KYPROLIS®

Carfilzomib (kar FILZ oh mib)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Kyprolis. It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Kyprolis against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What Kyprolis is used for

Kyprolis is a type of medicine used to treat patients with multiple myeloma (cancer of blood cells).

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

Ask your doctor if you have any questions about why it has been prescribed for you.

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

Before you are given it

When you must not be given it

Do not use Kyprolis if you have an allergy to:

- any medicine containing carfilzomib
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use it after the expiry date (EXP) printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor, nurse or pharmacist.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or nurse if you have, or have had, any of the following medical conditions before having Kyprolis:

- 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 which can indicate you have a low blood platelet count
- blood clots in your veins and small blood vessels

- any other major disease for which you were hospitalised or received medication.

Tell your doctor if you are pregnant, think you are pregnant, or if you or your partner intend to become pregnant.

Like most medicines of this kind Kyprolis is not recommended to be used during pregnancy.

Use birth control while using Kyprolis to ensure you or your partner do not become pregnant.

- **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.**

Discuss with your doctor what method of contraception to use whilst taking this medicine.

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, your partner becomes pregnant whilst you are using Kyprolis, or**

within 3 months of you stopping treatment with Kyprolis.

Your doctor will discuss the risks and benefits of using it while you are or your partner is pregnant.

Tell your doctor if you are breastfeeding or planning to breast feed.

It is not known whether Kyprolis passes into breast milk. You should not breastfeed during treatment with Kyprolis.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you are given Kyprolis.

Before starting Kyprolis, and during treatment, your doctor may do blood tests. This is to check the number of blood cells and how well your heart, kidneys and liver are working.

Your doctor or nurse will ensure you are getting enough fluids to avoid dehydration.

Taking other medicines

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

Tell your doctor, nurse or pharmacist if you are taking medicines used to prevent pregnancy.

These include

- oral contraceptives
- hormonal contraceptives.

Some medicines may be affected by Kyprolis or may affect how well it works.

You may need to use different amounts of your medicines, or take different medicines. Your doctor will advise you.

Read the CMI leaflets of all medicines you take in combination with Kyprolis.

This will help you understand the information related to those medicines.

How it is given

Treatment with Kyprolis will be under the supervision of a doctor. Your treatment with Kyprolis may be given to you by a doctor or nurse.

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

They may differ from the information contained in this leaflet.

How it is given

Kyprolis is dissolved in sterile water for injections. The solution is given as an infusion into your vein.

When it is given

One treatment cycle lasts 28 days, with Kyprolis given either once weekly or twice weekly.

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

How often it is given will depend on your treatment regimen.

When Kyprolis is given with lenalidomide and dexamethasone

In cycles 1-12, Kyprolis is administered on days 1, 2, 8, 9, 15 and 16.

After cycle 12, Kyprolis is administered on days 1, 2, 15 and 16.

When Kyprolis is given with dexamethasone

Kyprolis is administered on days 1, 8 and 15 in every cycle (once weekly) or days 1, 2, 8, 9, 15 and 16 in every cycle (twice weekly).

Ask your doctor if you want to know more about the treatment you will receive.

How much is given

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

How long to take it

Your doctor will decide how long you will use this medicine. This will depend on how you respond to treatment.

While you are using it

Things you must do

Tell any other doctors, nurses or pharmacists who treat you that you are taking this medicine.

Tell your doctor, nurse or pharmacist immediately if you experience any of the following while being treated with Kyprolis:

- severe chest pain, headache, which may be severe, confusion, seizures, blurred vision, visual loss, feeling sick (nausea) and vomiting, or severe anxiety
- shortness of breath, wheezing, difficulty breathing, rapid breathing or cough

- shortness of breath, irregular heartbeat, racing pulse, tiredness, dizziness and fainting spells
- blood clots in your veins and small blood vessels
- leg or arm swelling which could be a symptom of blood clots in the deep veins of the leg or arm
- chest pain or shortness of breath which may be a symptom of blood clots in the lungs
- 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
- blurred or double vision, loss of vision, difficulty speaking, weakness in an arm or leg, a change in the way you walk, problems with balance, persistent numbness, decreased sensation or loss of sensation, memory loss or confusion.

Your doctor or nurse will monitor you for signs and symptoms of these reactions.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of 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.

Things to be careful of

Be careful driving or operating machinery until you know how Kyprolis affects you.

Do not drive or operate machinery or engage in hazardous activities while you are being given Kyprolis if you experience fatigue, dizziness and/or fainting.

If you take too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you may have been given too much Kyprolis. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after being given Kyprolis.

All medicines can have side effects.

Specific side effects related to your heart, lungs, kidneys or a blockage of blood vessels by a blood clot can occur with Kyprolis. Ask your doctor, nurse or pharmacist to explain these possible side effects to you.

Your doctor has weighed the risks of using this medicine against the benefits they expect it to have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- numbness, tingling or decreased sensation in hands and/or feet
- difficulty sleeping (insomnia)
- anxiety
- constipation
- indigestion
- stomach pain
- decreased appetite
- toothache
- muscle weakness or spasms
- back pain, pain in limbs, bone, hands or feet
- blocked nose
- inflammation of the nose and throat

- runny or blocked nose, sneezing, facial pressure or pain
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- viral infection
- pain during urination or urgency to urinate
- redness of the skin or redness, irritation, pain or discomfort at the injection site
- increased sweating
- general feeling of illness or discomfort.

Tell your doctor, nurse or pharmacist as soon as possible if you notice any of the following and they worry you:

- change in voice or hoarseness
- pain in the throat
- nose bleed
- difficulty seeing
- dehydration
- rash, itchy skin, redness of the skin
- mild to severe nausea, vomiting, cramps and/or diarrhoea
- buzzing, hissing, whistling, ringing or other persistent noise in the ears

- watery diarrhoea 3 or more times a day for two or more days, with mild abdominal cramping and tenderness
- breathless with exertion or even at rest, with swelling of the legs, ankles and feet, bloating of the abdomen, cough whilst lying down, fatigue,
- heartbeats that feel rapid, pounding or fluttering and chest discomfort or pressure,
- dizziness, light-headedness and fainting.

Tell your doctor, nurse or pharmacist immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- chest pain, tightness or discomfort; may be sudden, sharp and become worse with deep breathing or coughing
- breathing problems such as shortness of breath, breathlessness, rapid breathing
- rapid, strong or irregular heartbeat
- pain in the liver (under the right ribcage), loss of appetite, nausea and vomiting
- yellowing of the skin and/or whites of the eyes, possibly with brown or orange urine
- abdominal pain or abdominal swelling
- headache

- confusion
- seizures, fits or convulsions
- visual loss, visual disturbance, blurred vision
- fever, chills
- cough, wheezing, phlegm, occasionally with blood
- fainting, weakness, dizziness, light headedness
- collapse
- numbness or weakness of the legs and arms
- difficulty swallowing
- slurred speech or loss of speech
- coughing or vomiting up blood
- coffee grounds or black sticky bowel motions (stools) or bright red blood in bowel motions
- pain behind breast bone, sometimes spreading to neck and shoulders, and sometimes fever
- severe stomach pain
- pain in joint or muscle, muscle ache
- facial flushing or swelling
- swelling of the hands, feet or ankles

- pain, swelling and tenderness in a limb, usually the calf
- bleeding or bruising more easily than normal
- little or no urine
- feeling sick (nausea), vomiting
- diarrhoea
- drowsiness
- fatigue
- watery diarrhoea 10 to 15 times a day, with abdominal cramping and pain, rapid heart rate, fever, nausea and dehydration
- severe muscle pain
- severe breathlessness
- cold, clammy and pale or mottled skin
- loss of consciousness.

These may be serious side effects of Kyprolis. You may need urgent medical attention or hospitalisation.

If any of the following happen, stop taking Kyprolis and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- 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
- faintness
- rapid pulse or sweating.

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

Tell your doctor or nurse if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After giving it

Storage

Kyprolis should be stored in a refrigerator at 2°C to 8°C, protected from light.

Keep it where children cannot reach it.

Disposal

Your doctor, nurse or pharmacist will dispose of this medicine.

Product description

What it looks like

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

Each pack contains one single-use vial.

Ingredients

Active ingredient: carfilzomib

- 60 mg carfilzomib in Kyprolis 60 mg vial
- 30 mg carfilzomib in Kyprolis 30 mg vial
- 10 mg carfilzomib in Kyprolis 10 mg vial

Inactive ingredients:

- sulfobutyl betadex sodium
- citric acid
- sodium hydroxide.

Kyprolis does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Kyprolis is supplied in Australia by:

Amgen Australia Pty Ltd

Level 11, 10 Carrington St

Sydney NSW 2000

Ph: 1800 803 638

www.amgenmedinfo.com.au

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Australian Registration Numbers:

60 mg vial: AUST R 283228

30 mg vial: AUST R 266773

10 mg vial: AUST R 288527