



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Kyprolis (*carfilzomib*)

An overview of Kyprolis and why it is authorised in the EU

What is Kyprolis and what is it used for?

Kyprolis is a cancer medicine used together with the medicines lenalidomide and dexamethasone or with dexamethasone alone, to treat multiple myeloma (a cancer of the bone marrow). It is given to adults who have received at least one previous treatment for their cancer.

Kyprolis contains the active substance carfilzomib. Multiple myeloma is rare, and Kyprolis was designated an 'orphan medicine' (a medicine used in rare diseases) on 3 June 2008. Further information on the orphan designation can be found here: ema.europa.eu/Find_medicine/Human_medicines/Rare_disease_designation.

How is Kyprolis used?

Kyprolis can only be obtained with a prescription and treatment must be supervised by a doctor experienced in the treatment of cancer.

Kyprolis is available as a powder to be made up into a solution for infusion (drip) into a vein. It is given in four-week treatment cycles, on days 1, 2, 8, 9, 15 and 16 of each cycle. From cycle 13 onwards, the doses on day 8 and 9 are omitted if Kyprolis is used with lenalidomide and dexamethasone. The dose is calculated using the patient's height and weight. After the first week the dose is increased if the side effects are manageable. Each infusion lasts 10 or 30 minutes, according to the dose. Treatment may need to be stopped or the dose reduced, if the disease gets worse or the patient has severe side effects.

For more information about using Kyprolis, see the package leaflet or contact your doctor or pharmacist.

How does Kyprolis work?

The active substance in Kyprolis, carfilzomib, is a proteasome inhibitor. This means that it blocks the proteasome, which is a system within the cells that breaks down proteins that are no longer needed. Cancer cells have an increased need to produce and break down proteins because they multiply



rapidly. When carfilzomib stops the proteasome from breaking down proteins in the cancer cells, the proteins build up and cause the cells to die, slowing down the growth of the cancer.

What benefits of Kyprolis have been shown in studies?

Kyprolis taken together with lenalidomide and dexamethasone has been compared with lenalidomide plus dexamethasone in one main study involving 792 patients with multiple myeloma whose disease had got worse after previous treatment. The study showed that Kyprolis is effective at prolonging the time patients lived without their disease getting worse (progression-free survival): patients receiving Kyprolis with lenalidomide and dexamethasone lived on average for 26.3 months without their disease getting worse, compared with 17.6 months for patients receiving lenalidomide plus dexamethasone.

Another study in 929 multiple myeloma patients whose disease had got worse after previous treatment compared the combination of Kyprolis and dexamethasone with bortezomib and dexamethasone. The study showed that the combination of Kyprolis and dexamethasone is more effective at improving progression-free survival than bortezomib and dexamethasone: patients receiving Kyprolis plus dexamethasone lived for an average of 18.7 months without their disease getting worse, compared with 9.4 months for patients receiving bortezomib and dexamethasone.

What are the risks associated with Kyprolis?

The most common side effects with Kyprolis (which may affect more than 1 in 5 people) are anaemia (low red blood cell counts), tiredness, nausea, diarrhoea, thrombocytopenia (low blood platelet counts), fever, dyspnoea (difficulty breathing), respiratory tract (airways) infection, cough and neutropenia (low levels of neutrophils, a type of white blood cell).

The most serious side effects include toxic effects on the heart, lungs and liver, and hypertension (high blood pressure) that can be severe. Other serious side effects are dyspnoea, acute kidney injury, tumour lysis syndrome (a complication due to the breakdown of cancer cells), infusion-related reactions, thrombocytopenia, internal bleeding, posterior reversible encephalopathy syndrome (a brain disorder that can cause headache, confusion, fits and loss of vision, and which may improve over time) as well as thrombotic microangiopathy and TTP/HUS (diseases involving problems with the blood clotting system).

Kyprolis must not be used in women who are breastfeeding. For the full list of side effects and restrictions, see the package leaflet.

Why is Kyprolis authorised in the EU?

The European Medicines Agency decided that Kyprolis' benefits are greater than its risks and it can be authorised for use in the EU. The Agency noted the unmet medical need for patients with multiple myeloma who no longer improve with the available therapies. It considered that the increase in time without the disease getting worse with Kyprolis was clinically meaningful. Regarding safety, although side effects, including severe effects, were seen with treatment involving Kyprolis, these were considered acceptable and manageable.

What measures are being taken to ensure the safe and effective use of Kyprolis?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Kyprolis have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Kyprolis is continuously monitored. Side effects reported with Kyprolis are carefully evaluated and any necessary action taken to protect patients.

Other information about Kyprolis

Kyprolis received a marketing authorisation valid throughout the EU on 19 November 2015.

Further information on Kyprolis can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports.

This overview was last updated in 03-2018.