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Kapruvia (*difelikefalin*)

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

What is Kapruvia and what is it used for?

Kapruvia is a medicine used to treat moderate to severe pruritus (itching) in adults with chronic kidney disease who are on haemodialysis (treatment with a machine that filters toxins from the blood).

Kapruvia contains the active substance difelikefalin.

How is Kapruvia used?

Kapruvia can only be obtained with a prescription and treatment should be given by a healthcare professional with relevant experience. The medicine is given as an injection into the vein at the end of a haemodialysis procedure. It is given three times per week and the dose depends on the patient's weight.

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

How does Kapruvia work?

Difelikefalin, the active substance in Kapruvia, is an opioid that bind to receptors (targets) on nerves and immune cells involved in controlling itching and inflammation. By binding to the receptors (called kappa opioid receptors), difelikefalin activates them, reducing inflammation that could lead to itchiness and decreasing the signals that lead to the feeling of itchiness itself.

What benefits of Kapruvia have been shown in studies?

Kapruvia was effective at reducing the severity of pruritus in two main studies involving adults experiencing moderate to severe itchiness associated with chronic kidney disease. The main measure of effectiveness was a self-reported reduction of the worst level of itchiness experienced in a day.

The first study involved 378 adults with chronic kidney disease who had been on haemodialysis for at least three months. Of the patients taking Kapruvia, 51% reported a reduction of at least three points on the itchiness scale, compared with 28% who were taking a placebo (dummy treatment).

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In the second study, involving 473 adults with chronic kidney disease who had been on haemodialysis for at least three months, 54% of the patients taking Kapruvia reported an improvement of at least three points on the itchiness scale, compared to 42% of the 236 taking a placebo.

What are the risks associated with Kapruvia?

The most common side effects with Kapruvia (which may affect up to 1 in 10 people) are sleepiness and paraesthesia (sensations like numbness, tingling, pins and needles). Less common side effects (which may affect up to 1 in 100 people) are dizziness, headache, nausea (feeling sick), vomiting, diarrhoea and mental status changes (such as feeling confused). Most of these side effects were mild or moderate.

For the full list of side effects of Kapruvia, see the package leaflet.

Why is Kapruvia authorised in the EU?

In the clinical trials, Kapruvia was shown to be effective at reducing the feeling of itchiness experienced by patients as a result of their lack of functioning kidneys. In addition, the side effects are considered manageable. Therefore, the European Medicines Agency decided that Kapruvia's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Kapruvia

Kapruvia received a marketing authorisation valid throughout the EU on 25 April 2022.

Further information on Kapruvia can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/kapruvia.

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