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Kinpeygo (*budesonide*)

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

What is Kinpeygo and what is it used for?

Kinpeygo is a medicine used to treat adults with primary immunoglobulin A nephropathy (IgAN) whose disease is at risk rapidly getting worse. IgAN is a disease where the kidneys gradually stop working and eventually fail, requiring patients to undergo dialysis or have a kidney transplant.

Kinpeygo is a 'hybrid medicine'. It is similar to a 'reference medicine' containing the same active substance, but is used for a different disease and is given in a different way. The reference medicine for Kinpeygo is Entocort.

IgAN is rare, and Kinpeygo was designated an 'orphan medicine' (a medicine used in rare diseases) on 18 November 2016. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu-3-16-1778.

Kinpeygo contains the active substance budesonide.

How is Kinpeygo used?

Kinpeygo can only be obtained with a prescription and is available as capsules to be taken by mouth.

The recommended dose is 16 mg once a day in the morning, at least one hour before a meal, for 9 months. A 9-month cycle can be repeated if deemed necessary by the treating doctor. When stopping treatment, the dose should be reduced to 8 mg once a day for 2 weeks, which may be further reduced to 4 mg once a day for an additional 2 weeks, at the discretion of the treating doctor.

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

How does Kinpeygo work?

IgAN is caused by the immune system (the body's natural defences) producing a faulty version of immunoglobulin A (IgA), a protein in the blood that identifies and attaches to specific foreign substances. In patients with this condition, faulty IgA builds up in the kidney, damaging them and preventing them from working properly.

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The active substance in Kinpeygo, budesonide, is a corticosteroid. Corticosteroids have a wide range of effects that suppress the immune system. In particular, Kinpeygo is designed to release budesonide when it reaches the intestine, where it reduces the production of faulty IgA and thereby reducing IgA build-up and damage to the kidneys.

What benefits of Kinpeygo have been shown in studies?

A main study involving 199 patients with IgAN showed that, after 9 months of treatment, patients taking Kinpeygo had a 31% reduction in proteinuria (excess protein in the urine, which can be a sign of kidney damage) compared with a 5% reduction in patients taking placebo (a dummy treatment). Additional data showed that the benefits of Kinpeygo were less evident in patients with less advanced disease; the use of Kinpeygo is therefore limited to patients at risk of their kidney function rapidly getting worse.

What are the risks associated with Kinpeygo?

The most common side effects with Kinpeygo are acne (which may affect around 1 in 10 people), and high blood pressure, peripheral or face oedema (build-up of fluids in the extremities or in the face) and dyspepsia (indigestion), each of which may affect around 1 in 20 people. In clinical trials, these side effects were of mild or moderate severity and resolved with time. For the full list of side effects of Kinpeygo, see the package leaflet.

Kinpeygo must not be used in patients with severe liver impairment (Child-Pugh Class C). For the full list of restrictions, see the package leaflet.

Why is Kinpeygo authorised in the EU?

Kinpeygo was shown to be effective at lowering the level of excess protein in the urine in patients with IgAN, indicating an improvement in kidney function. Treatment with Kinpeygo was generally well tolerated, and side effects were in line with the known safety profile of budesonide.

The European Medicines Agency therefore decided that Kinpeygo's benefits are greater than its risks and it can be authorised for use in the EU.

Kinpeygo has been given 'conditional authorisation'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Kinpeygo?

Since Kinpeygo has been given conditional authorisation, the company that markets Kinpeygo has to submit additional results from the main study, which is still ongoing, in order to confirm the effectiveness and safety of the medicine in patients with IgAN.

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

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

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

Other information about Kinpeygo

Kinpeygo received a conditional marketing authorisation valid throughout the EU on 15 July 2022.

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

This overview was last updated in 07-2022.