EMEA/H/C/005653

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). 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 used in people who have at least 1 g of protein in their urine per day or a urine protein-to-creatinine ratio of at least 0.8 g/g (another measure of protein levels in the urine).

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.

Kinpeygo is taken once a day for 9 months. The doctor may decide to repeat the 9-month cycle if necessary.

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.

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 reduces IgA build-up and damage to the kidneys.

What benefits of Kinpeygo have been shown in studies?

A main study involving 364 patients with IgAN showed that, after 9 months of treatment, patients taking Kinpeygo had a 34% 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). Long-term data showed that 15 months after the 9-month treatment period, patients who had received Kinpeygo had a 31% reduction in proteinuria compared with 1% for those who had received placebo. The study data also indicated that Kinpeygo slows the decline in kidney function, as seen in the change in estimated glomerular filtration rate (eGFR; a measure of how well the kidneys are working). A decrease in eGFR indicates a decline in kidney function. 15 months after the 9-month treatment period, eGFR had dropped by 7.5 ml/min/1.73m^2 in people who had received Kinpeygo, compared with 13.5 ml/min/1.73m^2 in those who had received placebo.

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What are the risks associated with Kinpeygo?

For the full list of side effects and restrictions with Kinpeygo, see the package leaflet.

The most common side effects with Kinpeygo include acne (which may affect around 1 in 10 people), and peripheral or facial oedema (build-up of fluids in the extremities or in the face), weight increase and increased levels of white blood cells, each of which may affect around 1 in 20 people. In clinical trials, these side effects were mild or moderate 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).

Why is Kinpeygo authorised in the EU?

Kinpeygo has been shown to be effective at lowering the level of excess protein in the urine in patients with IgAN, and also appears to slow the decline in kidney function in adults with this disease. 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 was originally given 'conditional authorisation'. The authorisation has now been switched to standard authorisation as the company has provided additional data requested by the Agency.

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 19 May 2022. The conditional marketing authorisation was switched to a standard marketing authorisation on 24 July 2024.

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 06-2024