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EPAR summary for the public

Jinarc

tolvaptan

This is a summary of the European public assessment report (EPAR) for Jinarc. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Jinarc.

For practical information about using Jinarc, patients should read the package leaflet or contact their doctor or pharmacist.

What is Jinarc and what is it used for?

Jinarc is a medicine used to treat adults with autosomal dominant polycystic kidney disease. This is an inherited condition in which numerous fluid-filled cysts develop in the kidneys, which eventually affect kidney function and can cause the kidneys to fail. Jinarc is for use in patients with normal to moderately reduced kidney function at the beginning of treatment with Jinarc and whose disease is progressing rapidly.

Jinarc contains the active substance tolvaptan.

How is Jinarc used?

Jinarc can only be obtained with a prescription and treatment must be started and monitored by a doctor experienced in treating autosomal dominant polycystic kidney disease and with knowledge about the risks of treatment with Jinarc.

Jinarc is available as tablets (15, 30, 45, 60 and 90 mg). It is taken twice a day in two unequal doses. Patients should be started with a dose of 45 mg in the morning and 15 mg in the evening (45+15 mg), and the dose should then be increased to 60+30 mg or 90+30 mg, depending on what the patient can tolerate. The morning dose should be taken at least 30 minutes before the morning meal, whereas the evening dose can be taken with or without food. Doses may need to be reduced in patients taking certain other medicines. Patients should drink plenty of water while on treatment.



For further information, see the package leaflet.

How does Jinarc work?

The active substance in Jinarc, tolvaptan, is a vasopressin-2-receptor antagonist: it works by blocking receptors in the kidneys to which the hormone vasopressin attaches. Vasopressin regulates the level of water and sodium in the body. In autosomal dominant polycystic kidney disease, it is thought that kidney cells do not respond normally to vasopressin, leading to the formation of fluid-filled cysts. By blocking vasopressin receptors in the kidneys, Jinarc can slow down cyst formation.

What benefits of Jinarc have been shown in studies?

Jinarc was shown to be effective at slowing down cyst formation in a main study involving 1,445 adults with autosomal dominant polycystic kidney disease who had rapidly progressing disease but normal or moderately reduced kidney function. In the study, Jinarc was compared with placebo (a dummy treatment) and the main measure of effectiveness was the change in kidney size after 3 years of treatment (a way of measuring the swelling caused by cyst formation). In patients taking placebo, the total size of the kidneys increased by 18.8% whereas in those taking Jinarc the increase was 9.6%. The effects of treatment were greatest in the first year.

What are the risks associated with Jinarc?

The most common side effects with Jinarc (which may affect more than 2 in 10 people) are thirst, polyuria (increase in urine production), nocturia (need to pass urine at night) and pollakiuria (increased need to pass urine during the day). Jinarc may increase blood levels of certain liver enzymes (a sign of possible liver problems). For the full list of all side effects reported with Jinarc, see the package leaflet.

Jinarc must not be started in certain patients with increased blood levels of liver enzymes or with signs or symptoms of liver injury. Blood tests to check the patient's liver function should be performed before starting treatment with Jinarc, and then repeated every month for 18 months and every three months thereafter. Patients should also be monitored for symptoms of liver injury (such as loss of appetite, nausea and vomiting, itching, tiredness and pain in the upper-right side of the belly) during treatment. Jinarc must not be used in patients who are anuric (cannot pass or have difficulty in passing urine), volume depleted (have reduced amounts of fluids in the body) and in patients who cannot perceive or respond to thirst. It must not be used in patients with hypernatraemia (increased sodium levels in the blood) and in pregnant and breastfeeding women. For the full list of restrictions, see the package leaflet.

Why is Jinarc approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Jinarc's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP noted the unmet need for treatments for autosomal dominant polycystic kidney disease and considered that Jinarc is effective at slowing down cyst formation and possibly the decline in kidney function in patients with the condition, although further long-term data are awaited. Regarding safety, while the most common side effects are manageable, the Committee identified liver toxicity as the most important risk with Jinarc, which was addressed by putting in place several measures (see below).

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

The company that markets Jinarc will provide patients and doctors expected to use the medicine with information on the risk of liver toxicity and on the importance of preventing pregnancy during treatment. The company will also carry out a study to further investigate the safety of the medicine, including the risk of liver toxicity, a study on the long-term effectiveness of the medicine, and a study on the effectiveness in patients with severely reduced kidney function.

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

Other information about Jinarc

The European Commission granted a marketing authorisation valid throughout the European Union for Jinarc on 27 May 2015.

The full EPAR for Jinarc can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Jinarc, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2016.