

Tolvaptan (15 mg, 30 mg, 45 mg, 60 mg, 90 mg Tablets)

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What Jinarc is used for

Jinarc is used to treat “autosomal dominant polycystic kidney disease” or “ADPKD” in adults with chronic kidney disease (CKD) stages 1 to 4 with evidence of rapidly progressing disease.

ADPKD progresses with growth of fluid-filled cysts in the kidneys which put pressure on surrounding tissues and reduce kidney function, possibly leading to kidney failure.

How Jinarc works

Jinarc, which contains the active substance tolvaptan, blocks the effect of vasopressin. Vasopressin is a hormone which regulates water absorption from the kidneys and is involved in the formation of cysts in the kidneys of ADPKD patients. By blocking the effect of vasopressin, Jinarc increases urine production and slows the growth of kidney cysts in patients with ADPKD. It also helps in reducing the symptoms of the disease.

Before you use Jinarc

-When you must not use it

Do not take Jinarc if:

- you are allergic to tolvaptan or any of the other ingredients of this medicine (see *Product description*) or if you are allergic to benzazepine or benzazepine derivatives (e.g. benazepril, conivaptan, fenoldopam mesylate or mirtazapine)
- you have been told that you have raised levels of liver enzymes in your blood which do not allow treatment with Jinarc
- you are unable to urinate or your

kidneys have stopped working (no urine production)

- you have any condition which is associated with a very low blood volume
- you have any condition that increases the level of sodium in your blood
- you have difficulty realising when you are thirsty or are unable to drink water
- you are unable or unwilling to comply with monthly blood test for checking liver function

-Before you start to use it

Talk to your doctor or pharmacist before taking Jinarc if:

- you suffer from liver disease
- you cannot drink enough water or if you have to limit your fluid intake or are at an increased risk of water loss
- you have an enlarged prostate or have difficulty urinating
- you suffer from too high or too low blood sodium
- you have diabetes
- you have high levels of uric acid in your blood (which may have caused gout)
- you have galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption

Jinarc contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Pregnancy and breastfeeding

You should not take Jinarc if you are trying to become pregnant or during pregnancy as it may result in side effects to you and developmental abnormalities in your unborn baby. Women of childbearing potential must use one effective method of pregnancy prevention at least 4 weeks before therapy is initiated, during therapy and even in the case of dose interruptions, and for at least a further 4 weeks after stopping Jinarc.

You should not breastfeed while taking Jinarc. Ask your doctor or pharmacist for advice before taking this medicine.

Jinarc is not recommended for paediatric use as it has not been adequately studied in this population. It is not known if Jinarc is safe or works in children.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

How to use Jinarc

-How much to use

Jinarc should be taken in two split and different doses every day. Your doctor will start treatment with Jinarc at 60 mg a day, in split doses of 45 mg and 15 mg. Your doctor might increase the dose to 90 mg (60 mg and 30 mg) and then to 120 mg (90 mg and 30 mg) over the following weeks.

If you are taking medication which belongs to a group called CYP3A inhibitors, your doctor might prescribe a lower daily dose of 15 mg or 30 mg.

-When to use it

The higher dose is taken upon waking, at least 30 minutes before the morning meal, and the lower dose should be taken 8 hours later.

Swallow the tablets whole with a glass of water and do not chew them. Avoid drinking grapefruit juice when taking Jinarc.

-How long to use it

Always take Jinarc exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

-If you forget to use it

If you forget to take your medicine, you should take the dose as soon as you remember on the same day. If you forget to take the medicine completely one day, you should just take your normal dose on the following day. You SHOULD NOT take a double dose to make up for forgetting to take individual doses.

-If you use too much (overdose)

If you have taken more tablets than your prescribed dose, **drink plenty of**

water and contact your doctor or your local hospital immediately. Remember to take the medicine pack with you so that it is clear what you have taken. Do not take any more Jinarc tablets until you have spoken to the doctor at your local hospital.

While you are using it

-Things you must do

Jinarc treatment should be started and monitored under the supervision of your doctor with expertise in managing ADPKD and a full understanding of the risks of Jinarc therapy including liver toxicity.

- Drink plenty of water or other watery drinks whether or not you feel thirsty

-Things you must not do

You should not drink grapefruit juice during your treatment with Jinarc.

-Things to be careful of

Jinarc may cause your liver not to work properly and increase the level of liver enzymes and bilirubin in your blood. Consult your doctor if you develop symptoms of nausea, vomiting, fever, tiredness, loss of appetite, pain in the abdomen, dark urine, jaundice (yellowing of skin or eyes), itching of your skin or joint and muscle pain with fever (flu like syndrome).

To check for any changes in your liver function, your doctor will conduct blood test once prior to starting treatment. Monthly blood tests are required during the first 18 months of treatment. After 18 months of treatment, blood tests can be conducted every 3 months.

Jinarc has minor influence on the ability to drive or use machines. When driving or using machines, occasional dizziness, tiredness or fatigue may occur.

Side effects

The following signs indicate that you might have potential liver problems:

- Tiredness
- Loss of appetite

- Pain in the abdomen
- Dark urine
- Yellowing of skin or eyes (jaundice)
- Severe dehydration
- Nausea
- Vomiting
- Itching
- Flu-like syndrome (joint and muscle pain)
- Fever

You or a family member should tell your doctor right away if you have any of these symptoms and seek advice from your doctor. You may need to get additional blood testing. Treatment with Jinarc may be stopped and may be restarted if the blood tests for liver function are normal.

Other side effects:

Very common (may affect more than 1 in 10 people)

- Excessive thirst
- Headache
- Dizziness
- Diarrhoea
- Dry mouth
- Increased need to urinate, or to urinate more frequently, even wake up at night to urinate
- Tiredness

Common (may affect up to 1 in 10 people)

- Water loss
- High levels of sodium, uric acid, and blood sugar
- Hard to fall asleep or stay asleep
- Altered sense of taste
- Fainting
- Rapid, strong, irregular heartbeat
- Difficult breathing
- Stomach ache
- Constipation
- Dry skin
- Rashes, itchiness
- Joint and muscle pain
- Tiredness, general weakness

If you experience any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Jinarc

-Storage

Store in the original package in order to protect from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer require. These measures will help protect the environment.

Product Description

-What it looks like

Jinarc 15 mg Tablet is a blue, triangular tablet debossed with “OTSUKA” and “15” on one side.

Jinarc 30 mg Tablet is a blue, round tablet debossed with “OTSUKA” and “30” on one side.

Jinarc 45 mg Tablet is a blue, square tablet debossed with “OTSUKA” and “45” on one side.

Jinarc 60 mg Tablet is a blue, modified rectangular tablet debossed with “OTSUKA” and “60” on one side.

Jinarc 90 mg Tablet is a blue, pentagonal tablet debossed with “OTSUKA” and “90” on one side.

Jinarc 15 mg Tablets:

Available in Aluminium / Aluminium foil unit dose blisters of 10 x 3 tablets. One pack with 30 Jinarc 15 mg tablets contain 3 blisters of 10 tablets.

Jinarc 30 mg Tablets:

Available in Aluminium / Aluminium unit dose blisters of 10 x 3 tablets. One pack with 30 Jinarc 30 mg tablets contain 3 blisters of 10 tablets.

Jinarc 15 mg + 45 mg Tablets

Available in PVC / Aluminium foil unit dose combination blisters with the split dose of a daily high dose / low dose mix regimen of 45 mg + 15 mg. Each combination blister strip contains 7 x 45 mg + 7 x 15 mg tablets. One pack with (14 / 28 / 56) Jinarc tablets contain (1 / 2 / 4) blisters with 7 x 15 mg + 7 x 45 mg tablets.

Jinarc 30 mg + 60 mg Tablets

Available in PVC / Aluminium foil unit dose combination blisters with the split dose of a daily high dose / low dose mix regimen of 60 mg + 30 mg. Each combination blister strip contains 7 x 60 mg + 7 x 30 mg tablets. One pack with (14 / 28 / 56) Jinarc tablets contain (1 / 2 / 4) blisters with 7 x 30 mg + 7 x 60 mg tablets.

Jinarc 30 mg + 90 mg Tablets

Available in PVC / Aluminium foil unit dose combination blisters with the split dose of a daily high dose / low dose mix regimen of 90 mg + 30 mg. Each combination blister strip contains 7 x 90 mg + 7 x 30 mg tablets. One pack with (14 / 28 / 56) Jinarc tablets contain (1 / 2 / 4) blisters with 7 x 30 mg + 7 x 90 mg tablets.

Not all packs may be marketed in your country.

- Ingredients:**- Active ingredient:**

The active substance of Jinarc is tolvaptan.

Each 15 mg Jinarc tablet contains 15 mg of tolvaptan.

Each 30 mg Jinarc tablet contains 30 mg of tolvaptan.

Each 45 mg Jinarc tablet contains 45 mg of tolvaptan.

Each 60 mg Jinarc tablet contains 60 mg of tolvaptan.

Each 90 mg Jinarc tablet contains 90 mg of tolvaptan.

-Inactive ingredients:

The other ingredients are maize starch, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Indigo

carmines (E 132) aluminium lake, low-substituted hydroxypropyl cellulose.

- MAL number(s):

Jinarc 15 mg Tablet:

MAL XXXXXXXXX

Jinarc 30 mg Tablet:

MAL XXXXXXXXX

Jinarc 15 mg + 45 mg Tablet:

MAL XXXXXXXXX

Jinarc 30 mg + 60 mg Tablet:

MAL XXXXXXXXX

Jinarc 30 mg + 90 mg Tablet:

MAL XXXXXXXXX

Manufacturer(s)

Otsuka Pharmaceutical Co., Ltd –
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Product Registration Holder

Otsuka Pharmaceuticals (Malaysia)
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