

If you forget to take Jinarc®

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 accidentally take more Jinarc® than prescribed

If you have taken more tablets than your prescribed dose, drink plenty of water and contact your doctor or treatment centre immediately. Remember to take the medicine 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 treatment centre.

What important side effects of Jinarc® should I be aware 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 signs that could indicate potential liver problems such as: 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 tests:

When	Prior to starting treatment, at 2 weeks and 4 weeks after starting	First 18 months of treatment	After 18 months of treatment
Frequency of blood tests	Once	Monthly	Every 3 months



What should I do if I experience any of these signs?

You should inform your doctor immediately if you experience any of the signs mentioned above and seek advice from your doctor. You may need to get additional blood testing. Treatment with Jinarc® will be stopped and may be restarted if the blood tests for liver function are normal.

Is it safe to take Jinarc® while trying to become pregnant, during pregnancy or while 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.

What should I do if I become pregnant or think I may be pregnant while taking Jinarc® or within 30 days after stopping Jinarc®?

You should stop taking Jinarc® immediately and inform your prescribing doctor immediately so that your pregnancy can be monitored.



Patient Education Brochure

*This document has been approved by HSA as of 23-09-2022
Version 1.0*

Otsuka Pharmaceuticals (Singapore) Pte. Ltd.
2 Havelock Road, #05-15, Havelock 2, Singapore 059763



Contents

What is the purpose of this brochure?	1
What is Jinarc®?	1
Which patients are not eligible for treatment with Jinarc®?	2
Which patients should take special care when taking Jinarc®?	2
How should I take Jinarc®?	2-3
Is it important to drink plenty of fluids when taking Jinarc®?	3
If you forget to take Jinarc®	4
If you accidentally take more Jinarc® than prescribed	4
What important side effects of Jinarc® should I be aware of?	4
What should I do if I experience any of these signs?	5
Is it safe to take Jinarc® while trying to become pregnant, during pregnancy or while breastfeeding?	5
What should I do if I become pregnant or think I may be pregnant while taking Jinarc® or within 30 days after stopping Jinarc®?	5

What is the purpose of this brochure?

This Patient Education Brochure is provided by Otsuka Pharmaceuticals (Singapore) Pte. Ltd. for patients with autosomal dominant polycystic kidney disease (ADPKD) who are receiving treatment with Jinarc® (tolvaptan).

This brochure will:

- Explain what Jinarc® is, what medical condition it is used for and how it should be used
- Provide important safety information
- Help you to understand potential side effects of Jinarc® and what to do if they occur.

This brochure provides important information about Jinarc®. Please consult your doctor if you have any questions about your treatment with Jinarc®.

What is Jinarc®?

You have been prescribed Jinarc® because you have “autosomal dominant polycystic kidney disease” or “ADPKD”. This disease 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. Jinarc® is used to treat ADPKD in adults with chronic kidney disease (CKD) with evidence of rapidly progressing disease.

Jinarc® contains the active substance tolvaptan which 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.

Which patients are not eligible for treatment with Jinarc®?

You **should not take** Jinarc® if any of the following applies to you:

- you are allergic to tolvaptan or any of the other ingredients of this medication including lactose, 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 a condition which is associated with a very low blood volume
- you have a 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 planning to get pregnant, are pregnant or breastfeeding
- you are unable or unwilling to comply with monthly blood test for checking liver function.
- you are taking medication which can increase the effect of Jinarc®

Which patients should take special care when taking Jinarc®?

You should **take special care** and tell your doctor before and while taking Jinarc® if any of the following applies to you:

- you suffer from liver disease
- you cannot drink enough water or if you have to limit your fluid intake or you 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.

Please ask your doctor if you are not sure if any of these apply to you.

How should I take Jinarc®?

You should always take Jinarc® exactly as your doctor has told you. Please check with your doctor or pharmacist if you are not sure.

Jinarc® needs to be taken in two split and different doses every day. For the treatment in ADPKD, the total daily dose is usually between 60mg to 120mg.

Your doctor will start treatment with Jinarc® at 60mg a day, in split doses of 45mg and 15mg. 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 with or without meals. Your doctor might increase the dose to 90mg (60mg and 30mg) and then to 120mg (90mg and 30mg) over the following weeks. It is important to tell your doctor if you are taking any medicines or herbal treatments or supplements of any sort. If you are taking other medication which can increase the effects of Jinarc®, your doctor might prescribe a lower daily dose of 30mg.

You should swallow the tablets whole with a glass of water and should not chew them. **Do not drink grapefruit juice while taking Jinarc®.**

Is it important to drink plenty of fluids when taking Jinarc®?

Jinarc® also causes water loss because it increases your urine production. This water loss may result in side effects such as dry mouth and thirst or even more severe side effects like kidney problems or severe dehydration.

Symptoms of dehydration may include:

- Increased thirst
- Dry skin
- Dry mouth
- Dizziness
- Feeling tired or sleepy
- Rapid heart rate
- Decreased urination
- Confusion
- Headache
- Poor skin elasticity

It is important that you contact your doctor if you develop any of the symptoms listed above.

You should drink plenty of water or other watery drinks whether or not you feel thirsty in order to avoid excessive thirst or dehydration. You should drink 1 - 2 glasses of fluid before bedtime and drink more if you pass urine during the nighttime. Special care must be taken if you have a condition that increases the risk of water loss, e.g. in case of vomiting or diarrhoea.

