

Tolvaptan (JINARC®) RMP (RISK MANAGEMENT PROGRAM) PATIENT GUIDE

Patients: Your doctor will explain this patient guide to you. Ask questions if you have any. Keep this guide for important safety information about the serious risks of (Tolvaptan) JINARC®.

Healthcare Providers: Go over this patient guide with your patient and give them a copy to take home.

WHAT IS (TOLVAPTAN) JINARC®?

(TOLVAPTAN) JINARC® is a prescription medicine used to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). It is not known if (TOLVAPTAN) JINARC is safe and effective in children.

WHAT IS THE MOST SERIOUS RISK OF (TOLVAPTAN) JINARC®?

(TOLVAPTAN) JINARC® can cause serious liver problems that can lead to the need for a liver transplant or can lead to death.

WHAT IS THE JINARC® RMP?

JINARC® RMP is a safety monitoring program required by Otsuka to manage the risk of serious and potentially fatal liver injury associated with (TOLVAPTAN) JINARC® to make sure the benefits outweigh the risks. The program educates patients and healthcare providers about the risks of (TOLVAPTAN) JINARC®. Requirements of the JINARC® RMP include the following:

1. Requires patients and healthcare providers to be enrolled and certified to receive and prescribe (TOLVAPTAN) JINARC®.
2. Before and during treatment, your healthcare provider will check your liver function with blood tests.
3. (TOLVAPTAN) JINARC® is only available through the JINARC® RMP.

HOW DO I START TREATMENT WITH (TOLVAPTAN) JINARC®?

1. Receive and read the Patient Guide
2. Agree to have important blood tests before you start, and regularly while you are taking (TOLVAPTAN) JINARC® - to monitor your liver health
3. Call the ADPKD Hotline to enroll in the JINARC® RMP and share a copy of your latest Liver Function Test result (ALT, AST, bilirubin) and JINARC® prescription. The team will ask for your consent before asking for your personal information, LFTs, and prescription.

ADPKD Hotline (Monday-Friday 8AM-6PM)

Globe: 0917 801 5689

Smart: 0998 841 3379

Email: otsukapap@globoasiatico.com

4. Upon successful enrollment, you will be referred to the exclusive pharmacy where you can purchase Tolvaptan (Jinarc®). For the first 18 months of treatment, only a maximum of 30-day supply of tablets can be purchased at a time and the Liver Function Test (AST, ALT, bilirubin) & prescription must be updated monthly. After the first 18 months, monitoring and updating will be every 3 months.

WHO SHOULD NOT TAKE (TOLVAPTAN) JINARC®?

Do not take (TOLVAPTAN) JINARC® if you:

1. have a history of liver problems*,
2. cannot feel thirst or unable to drink
3. have high or low sodium levels,
4. are dehydrated,
5. are allergic to Tolvaptan, or
6. are unable to urinate.

**This excludes those with polycystic liver disease who have liver problems.*

WHAT DO I NEED TO DO BEFORE & WHILE I AM BEING TREATED WITH (TOLVAPTAN) JINARC®?

- Take liver function test (must have AST, ALT, bilirubin):
 - Before my treatment begins, and then
 - On the 2nd and 4th week of the 1st month
 - Every month from the 2nd to 18th month
 - Every 3 months from then on

On the 2 nd and 4 th week of the 1 st month				Monthly from the 2 nd to 18 th month															Every 3 months thereafter					
WEEK				MONTH															QUARTER					
1	2	3	4	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	1	2	3	4
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	

- Contact your healthcare provider if you experience any side effects or symptoms after taking (TOLVAPTAN) JINARC®
- Inform the ADPKD Hotline if I change my healthcare provider, contact information, or stop taking JINARC®.

WHAT ARE THE SIGNS AND SYMPTOMS OF SERIOUS LIVER INJURY?

You or your family member should contact your healthcare provider right away if you have any of the following symptoms:

- feeling tired
- loss of appetite
- nausea
- right upper stomach (abdomen) pain or tenderness
- vomiting
- fever
- rash
- itching
- yellowing of the skin and white part of the eye (jaundice)
- dark urine

**For Full Prescribing Information, please see Tolvaptan (Jinarc®) package Insert.*

Reference: Tolvaptan (Jinarc®) [Package Insert]. Tokushima, Japan; OPC; December. 2022.



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