

Tolvaptan (JINARC®) RMP PRESCRIBER GUIDE

JINARC® BOXED WARNING*: Tolvaptan (JINARC®) can cause serious and potentially fatal liver injury, including acute liver failure requiring transplantation. To reduce this risk, **ALT, AST, and bilirubin levels** should be measured **before starting treatment**, at **2 and 4 weeks after starting**, and **monthly for the first 18 months** and **every 3 months** after that. If laboratory abnormalities or signs of liver injury occur, prompt action can help reduce but not eliminate the risk of liver damage. Due to the risks, JINARC is only available through a restricted distribution program called the JINARC RMP.

DEFINITION OF SERIOUS AND POTENTIALLY FATAL LIVER INJURY*

Report any of the following liver injury events as serious and potentially fatal:

- Development of any liver injury leading to Liver transplantation or resulting to any fatal/life-threatening outcome.
- Development of any liver injury events meeting any of the laboratory criteria presented below:
 - **ALT or AST levels greater than 8 times** the ULN (Upper Limit of Normal)
 - **ALT or AST levels greater than 5 times** the ULN for more than two weeks
 - **ALT or AST levels greater than 3 times** the ULN and TBL levels greater than 2 times the ULN or INR (International Normalized Ratio) levels **greater than 1.5** (TBL levels can be measured within 30 days of the ALT elevation) or
 - **ALT or AST levels greater than 3 times** the ULN and the appearance of fatigue, nausea, vomiting, right upper quadrant pain or tenderness, fever, rash, and/or eosinophilia (>5%)

WHAT IS THE JINARC RMP?

The JINARC RMP is a strategy required by Otsuka to manage the risk of serious liver injury associated with the use of JINARC. JINARC can cause serious liver injury, so regular monitoring and liver enzyme (ALT, AST, TBL) testing is required before and during treatment. Prompt recognition and response to symptoms can help reduce the risk of more serious liver injury. To ensure safe use, JINARC is only available through the JINARC RMP, a restricted distribution program.

WHAT ARE THE REQUIREMENTS OF JINARC RMP?

To prescribe JINARC, healthcare providers need to follow these steps:

1. Complete a **one-time certification process**.
2. Counsel patients and **conduct baseline liver enzyme** (ALT, AST, TBL) **testing** before enrolling them in the RMP program and writing a prescription.
3. **Continuously monitor patients**, conduct liver enzyme (ALT, AST, TBL) testing at 2 and 4 weeks after starting and monthly during the first 18 months of treatment, and every 3 months thereafter.

HOW DOES A PRESCRIBER BECOME CERTIFIED?

To prescribe JINARC safely, follow these steps:

1. Read the educational materials on JINARC found in the website to understand the risk of severe and potentially fatal liver injury, which includes the **Prescribing Information** and **Prescriber Guide**.
2. Pass the **Prescriber Knowledge Assessment**. Once you pass, the JINARC RMP will send a notification of your certification to your email.

HOW DO I ENROLL A PATIENT IN THE JINARC RMP?

To enroll a patient in the JINARC RMP:

1. Counsel the patient on the risks and monitoring requirements [before your first dose, 2 weeks and 4 weeks after your first dose, and monthly for the first 18 months of treatment, and every 3 months thereafter] using the **Patient Guide**.
2. Order and evaluate **liver function test** (LFT such AST, ALT, TBL) before writing the prescription.
3. Once qualified, inform the patient to contact **JINARC Patient Support Team**.

ONCE A PATIENT IS ON JINARC, HOW OFTEN SHOULD I MONITOR PATIENTS?

1. Order and review liver laboratory tests (**liver transaminases** and **total bilirubin**) at specific time points after treatment initiation, as follows:
 - At **2 weeks** and **4 weeks** after treatment initiation

- **Monthly** for the first 18 months of treatment
 - **Every 3 months** thereafter
2. Assess the patient's liver function and determine the appropriateness of continuing treatment.

HOW SHOULD I REPORT LIVER ADVERSE EVENTS?

- Healthcare providers must notify the OPPI-Pharmacovigilance for any serious or potentially fatal liver issues.
- Contact Details: insert Magellan / One Quest Program number / hotline or OPPI-PV (oppi-pv@otsuka.com.ph) 09998869910.

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



Otsuka (Philippines) Pharmaceutical, Inc.

Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.

Distributed and marketed by Otsuka (Philippines) Pharmaceutical, Inc., Makati, Philippines.

JINARC is a registered trademark of Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.

©2023 Otsuka (Philippines) Pharmaceutical, Inc.

March 2023

Promo Mat. Code