

Pr JINARC® Controlled Hepatic Safety Monitoring and Distribution Programme

Liver Function Test Fax-Back Form

Below is an example of a form you will receive from the JINARC Hepatic Safety Monitoring and Distribution (HSMD) Programme. Once received, fill it out with your patient's most recent liver function test (LFT) results and fax back to the HSMD Programme.

To: <<Fax Number>>

Date of Report << YYYY-MM-DD >>

From: Pr JINARC® Controlled Hepatic Safety Monitoring and Distribution Programme [1-844-254-6272]

Dear Dr. <<First Name Last Name>>, <<[JINARC ID: Dr. JINARC ID Number]>>

Our records indicate that a liver function test (LFT) report is due for each of the following patients treated with Pr JINARC®. In accordance with Health Canada requirements, the Hepatic Safety Monitoring and Distribution (HSMD) Programme must ensure follow-up and collection of transaminase results status for all patients treated with JINARC to facilitate its safe use. Please complete this form based on the most recent LFT results of your patient's transaminase levels and fax the form(s) to the JINARC HSMD Programme at 1-844-3JINARC (1-844-354-6272) by <<YYYY-MM-DD>>. Please note, if this report is not returned by its due date, your office will receive a follow-up call requesting this information as per the Programme requirements.

JINARC Active Patients

Patient Identifiers	ALT/AST Monitoring Frequency	ALT/AST Results Received?	Were ALT/AST levels > 3x ULN?	JINARC Treatment Status (please select, if applicable)	Please check if patient meets Product Monograph guidelines for permanent JINARC discontinuation ^{2,3}
Initials: <i>prepopulated</i> DOB: <i>prepopulated</i> JINARC ID #: <i>prepopulated</i>	<input type="checkbox"/> Monthly <input type="checkbox"/> Q3 months <input type="checkbox"/> Q6 months <i>(prepopulated)</i>	<input type="checkbox"/> Yes _____ YYYY-MM-DD <input type="checkbox"/> No	<input type="checkbox"/> Yes ¹ <input type="checkbox"/> No	<input type="checkbox"/> Treatment Interrupted <input type="checkbox"/> Treatment Discontinued _____ YYYY-MM-DD	<input type="checkbox"/>

¹ At the onset of symptoms or signs consistent with hepatic injury, or if abnormal ALT or AST increases are detected, JINARC administration must be immediately interrupted and repeat liver tests, i.e., ALT, AST, total bilirubin, alkaline phosphatase, must be obtained as soon as possible, ideally within 48-72 hours. Testing should continue at an increased frequency until symptoms/signs/laboratory abnormalities stabilise or resolve, at which point cautious re-initiation of JINARC may be considered.

² JINARC supply will be permanently discontinued if any of the following conditions are met: ALT or AST > 8-times ULN OR ALT or AST > 5-times ULN for more than 2 weeks OR ALT or AST > 3-times ULN and total bilirubin > 2-times ULN or INR > 1.5 OR ALT or AST > 3-times ULN with persistent symptoms of hepatic injury.

³ Permanent discontinuation from receiving tolvaptan is a contraindication and so once a patient has been permanently discontinued from receiving tolvaptan, treatment must never be restarted. The permanent discontinuation status of patients should be verified prior to initiation with tolvaptan.

Note: Prescribers should report any adverse event associated with JINARC to Otsuka Canada Pharmaceutical Inc. at 1-877-341-9245.

JINARC Interrupted Patients

Based on information the Programme has previously received, the following patients have had their treatment with JINARC interrupted. Please indicate if these patients will be resuming treatment.

Patient Identifiers	Date of Treatment Interruption	Will treatment be re-initiated?	Anticipated Re-initiation Date of JINARC
Initials: <i>prepopulated</i> DOB: <i>prepopulated</i> JINARC ID #: <i>prepopulated</i>	<i>Prepopulated</i> _____ YYYY-MM-DD	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Please provide date, if available: _____ YYYY-MM-DD

By signing this form, I confirm the prepopulated information to be correct, and I attest that the information provided on page X to page Y to be accurate and true.

Please print name: _____

Signature of prescriber or delegate: _____

X _____ Date: _____
 YYYY-MM-DD

If you have any questions, please do not hesitate to call us.

Thank you,

JINARC Hepatic Safety Monitoring and Distribution Programme Team

Programme Phone: 1-844-2JINARC (1-844-254-6272)
 Programme Fax Number: 1-844-3JINARC (1-844-354-6272)

For important safety information and access to educational material, please visit JINARC.ca

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