PrLUPIN-TOLVAPTAN LUPIN GENESIS PROGRAM

Liver Function Test Fax-Back Form

Following is the form you will receive from the LUPIN-TOLVAPTAN Lupin Genesis program. Please enter the most recent liver function test (LFT) results of your patients and fax back to the Lupin Genesis program (1-866-488-1457).

To: <<Fax Number>>
From: LUPIN-TOLVAPTAN Lupin Genesis program (1-866-488-6017)

Date of the report: <<YYYY-MM-DD>>

Dear Dr. << First name Last Name>>, << LUPIN-TOLVAPTAN ID Number>>

According to our records, an LFT report is due for each of the following patients treated with LUPIN-TOLVAPTAN. According to Health Canada, the Lupin Genesis program must ensure follow-up and collection of transaminase results for all patients taking LUPIN-TOLVAPTAN to ensure its safe use. Please fill in this form based on the most recent transaminase levels of your patients' LFT results and fax the form to the LUPIN-TOLVAPTAN Lupin Genesis program at 1-866-488-1457 by **<<YYYY-MM-DD>>**. In case of failure to send back this report by its due date, a follow-up call will be given to your office requesting this information as per Lupin Genesis program requirements.

Active patients on LUPIN-TOLVAPTAN

Patient details	ALT/AST monitoring frequency	ALT/AST results received?	Were ALT/ AST levels > 3 x ULN?	LUPIN-TOLVAPTAN treatment status (please select, if applicable)	Please check if patient meets Product Monograph guidelines for permanent discontinuation of LUPIN-TOLVAPTAN[2,3]
Initials: *prepopulated* **DOB:** *prepopulated* **LUPIN-TOLVAPTAN ID #:** *prepopulated*	☐ Monthly ☐ 3 Months ☐ 6 Months *(prepopulated)*	☐ Yes _____ (YYYY-MM-DD) ☐ No	☐ Yes[1] ☐ No	☐ Treatment interrupted ☐ Treatment discontinued _____ (YYYY-MM-DD)	☐

[1] At the onset of signs or symptoms of hepatic injury or if abnormal increase in transaminase level is detected, LUPIN-TOLVAPTAN treatment must be immediately interrupted and liver function tests (ALT, AST, total bilirubin, alkaline phosphatase) should be repeated as soon as possible (ideally within 48–72 hours). Testing should be continued until symptoms or signs or laboratory abnormalities settle down or resolve, at which point cautious re-initiation of LUPIN-TOLVAPTAN should be considered.

[2] If ALT or AST levels are > 8 times ULN OR ALT or AST levels are > 5 times ULN for more than 2 weeks OR ALT or AST levels are > 3 times ULN and total bilirubin is > 2 times ULN or INR is > 1.5 OR ALT or AST levels are > 3 times ULN with persistent symptoms of liver injury, then LUPIN-TOLVAPTAN will be permanently discontinued.

[3] Permanent discontinuation of LUPIN-TOLVAPTAN is a contraindication, and so if LUPIN-TOLVAPTAN is permanently discontinued for a patient, treatment must never be re-initiated. Permanent discontinuation status of patients should be verified prior to initiation of treatment with LUPIN-TOLVAPTAN.

Note: Any adverse event associated with LUPIN-TOLVAPTAN should be reported to **1-866-488-6017**.

Details of patients with interrupted LUPIN-TOLVAPTAN:

According to previous information received from the Lupin Genesis program, below are the details of patients with interrupted LUPIN-TOLVAPTAN treatment.

Patient identifier	Date of interruption of treatment	Will treatment be re-initiated?	Anticipated date of re-initiation of treatment with LUPIN-TOLVAPTAN
Initials: *prepopulated* **DOB:** *prepopulated* **LUPIN-TOLVAPTAN ID #:** *prepopulated*	*Prepopulated* _____ (YYYY-MM-DD)	☐ Yes ☐ No ☐ Unknown	Please provide date if available: _____ (YYYY-MM-DD)

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

Please print name: _____

Signature of Prescriber/Delegate:

X _____ Date: _____ (YYYY-MM-DD)

If you have any queries, feel free to call us.

Thank you,

LUPIN-TOLVAPTAN Lupin Genesis program team

Lupin Genesis program phone number: **1-866-488-6017**
Fax number: **1-866-488-1457**
For important safety information and for educational material, please visit: www.LupinGenesis.com