

Adverse events or laboratory abnormalities suggestive of serious and potentially fatal liver injury must be reported to the REMS.

Adverse events or laboratory abnormalities suggestive of serious and potentially fatal liver injury are:

- ALT or AST >3xULN and TBIL >2x ULN
- ALT or AST >10xULN with or without TBIL elevation
- TBIL >2xULN without changes in ALT or AST
- Liver Transplantation
- Death

You can complete this form online at [www.TURALIOREMS.com](http://www.TURALIOREMS.com), or fax it to the TURALIO REMS Call Center at 1-833-TRL-REMS or call the TURALIO REMS Call Center at 1-833-TURALIO (1-833-887-2546) to provide the information.

Patient Information		
First Name:	Last Name:	Birthdate (MM/DD/YYYY):
Address has not changed: <input type="checkbox"/> or update below:		
Address Line 1:		
Address Line 2:		
City:	State:	ZIP Code:
Prescriber Information		
First Name:	Last Name:	NPI #:
Practice/Facility Name:		
Address has not changed: <input type="checkbox"/> or update below:		
Address Line 1:		
Address Line 2:		
City:	State:	ZIP Code:
Phone:		



## Liver Adverse Event Reporting

1. What event triggered this report?

2. Report the following labs if they were obtained. If labs were not obtained, indicate "not applicable."

Laboratory Test	Maximum Value and Units	Reference Range Min and Max and Units	Resolved Y/N
AST or SGOT			
ALT or SGPT			
Alkaline Phosphatase			
GGT			
Total Bilirubin			
Direct Bilirubin			
PT/INR			
Albumin (minimum)			
Viral Hepatitis Status	Tests performed, date tested, and results:		



Daiichi-Sankyo

Phone: 1-833-TURALIO

www.TURALIOREMS.com

Fax: 1-833-TRL-REMS



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## Patient Hepatic Monitoring Information

3. Was a hepatology referral obtained?  Yes  No

4. Were any of the following procedures performed?

Procedure <sup>1</sup>	Yes or No
Liver Ultrasound	
Other Imaging of the Liver	
Liver Biopsy	
ERCP	
Hospitalization	
Liver Dialysis	
Other	

<sup>1</sup> If the patient had imaging or the procedure more than once, please provide information about each individual procedure or imaging

5. Medications prescribed to treat event: (circle) Yes or No

6. What is the current status of the liver adverse event (check one)?

- Resolved, date resolved: \_\_\_\_\_
- Ongoing, date of last assessment: \_\_\_\_\_
- Resolved with sequelae, describe: \_\_\_\_\_
- Liver transplant, date: \_\_\_\_\_
- Patient death, date: \_\_\_\_\_

## Signature

Printed Name:	Title:
Signature:	Date (MM/DD/YYYY):

Prescribers should always report all adverse events by contacting the REMS at 1-833-TURALIO, Daiichi Sankyo, Inc. at 1-877-4DS-PROD (1-877-437-7763) or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.



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