TURALIO® REMS

Liver Adverse Event Reporting Form

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 (or DBL>1.5xULN) without changes in ALT or AST**
- **ALP >2xULN with GGT>2xULN**
- **Liver Transplantation**
- **Death**

You can complete this form online at 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: ☐ 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: ☐ 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	Date of tests: _____	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:		

Patient Hepatic Monitoring Information

3. Was a hepatology referral obtained? ☐ Yes ☐ No

4. Were any of the following procedures performed?

Procedure[1]	Yes or No
Liver Ultrasound	☐ Yes ☐ No
Other Imaging of the Liver	☐ Yes ☐ No
Liver Biopsy	☐ Yes ☐ No
ERCP	☐ Yes ☐ No
Hospitalization	☐ Yes ☐ No
Liver Dialysis	☐ Yes ☐ No
Other	☐ Yes ☐ No

[1] 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: ☐ Yes ☐ 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 or call 1-800-FDA-1088.