

Assess the patient by obtaining liver tests as stated in the Prescribing Information. Please order these tests for each of your patients taking TURALIO, and use this form to confirm that the testing has been done and reviewed.

You can complete this form online at www.TURALIOREMS.com, fax it to the TURALIO REMS Program Call Center at 1-833-TRL-REMS or E-mail it to Enroll@TURALIOREMS.com.

This form must be completed and submitted for each patient:

- **Every month for the first three months of treatment**
- **Month 6, 9 and 12 of treatment**
- **Every 6 months thereafter**

Note: The completion of the laboratory tests (see frequency below) and the submission of the Patient Status Form (per the schedule shown above) are done at different intervals.

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:		
Hepatic Monitoring Information		
Obtain liver tests as follows: <ul style="list-style-type: none"> • Weekly for the first 8 weeks of treatment • Every 2 weeks for the next month • Every 3 months thereafter 		
1. Is the patient still under your care? <input type="checkbox"/> Yes <input type="checkbox"/> No		
2. Is the patient alive? <input type="checkbox"/> Yes <input type="checkbox"/> No		
3. Are you monitoring the patient as recommended in the Prescribing Information? <input type="checkbox"/> Yes <input type="checkbox"/> No		
4. Is the patient continuing TURALIO? <input type="checkbox"/> Yes <input type="checkbox"/> No Withheld, reason: _____ Discontinued, reason: _____		



Since starting TURALIO or since submission of the last Patient Status Form, whichever is later, has the patient experienced any of the following:

Laboratory Tests

5. ALT or AST >3x ULN and TBIL >2x ULN? Yes No
6. ALT or AST > 10x ULN with or without TBIL elevation? Yes No
7. TBIL >2x ULN without changes in ALT or AST? Yes No

Procedures/Imaging/Referrals

8. Liver ultrasound: Yes No
9. CT or MRI/MRA/MRV of the liver: Yes No
10. Liver biopsy: Yes No
11. Hepatology evaluation/referral: Yes No
12. Referral for liver transplantation: Yes No
13. Endoscopic retrograde cholangiopancreatography (ERCP): Yes No
14. Hepatobiliary iminodiacetic acid (HIDA) scan: Yes No
15. Hospitalization for management of liver toxicity: Yes No
16. Other procedure/referral: Yes No Describe: _____

Medications prescribed to treat liver injury:

17. Were steroids used? Yes No
18. Was ursodeoxycholic acid? Yes No
19. Other? Yes No Describe: _____

If the answer to any of the questions on this page is Yes, submit a Liver Adverse Event Reporting Form to the REMS.

Date Submitted: _____

Other Medications: Complete if Yes to any of the above questions

20. Concomitant prescription medications while on TURALIO treatment: _____

21. Concomitant non-prescription medications or herbal and dietary supplements while on TURALIO treatment: _____

Prescriber Signature:

Prescriber 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.



Phone: 1-833-TURALIO

www.TURALIOREMS.com

Fax: 1-833-TRL-REMS



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