

ZINBRYTA REMS Program Patient Status Form



This form must be completed every 90 days for all patients treated with ZINBRYTA during treatment and every 90 days for 6 months after discontinuation. Please complete this form by <DATE> and return to the ZINBRYTA REMS Program. You may also be contacted for additional information in response to answers provided on this form.

Please submit this completed form to the ZINBRYTA REMS Program via fax or mail:

1-855-474-3067 5000 Davis Drive, PO Box 13919, Research Triangle Park, NC 27709

If you have any questions regarding the ZINBRYTA REMS Program, call: 1-800-456-2255

<Patient Therapy Status> Patient Therapy Status	<Today's Date> Today's Date
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PRESCRIBER INFORMATION

<Prescriber Name> Prescriber Name		
<Prescriber Address> Prescriber Address		
<City> City	<State> State	<ZIP> ZIP
<Prescriber Enrollment ID> Prescriber Enrollment ID		

PATIENT INFORMATION

<Patient Name> Patient Name	
<Patient Enrollment ID> Patient Enrollment ID	<DOB> Patient Date of Birth

Is the above-named patient still under the care of <Prescriber Name>? Yes No
If No, please indicate the name of the prescriber now responsible for this patient's care

<input type="checkbox"/> Prescriber Name	<input type="checkbox"/> Prescriber Number	<input type="checkbox"/> Unknown
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PATIENT STATUS

1. This patient has completed required liver testing during the last 90 days: Yes No

2. Has this patient been diagnosed with any of the following that you have *not already* reported to Biogen in the last 90 days?

a. Hepatic injury Yes No
· May include elevated liver enzymes and/or total bilirubin:
- ALT or AST >5x ULN **OR**
- Total bilirubin >2x ULN **OR**
- ALT or AST ≥3xULN but <5xULN and total bilirubin >1.5xULN but <2xULN
· Or a suspected or confirmed diagnosis (e.g. autoimmune hepatitis)

b. Immune-mediated disorders Yes No
· May include skin reactions, lymphadenopathy, non-infectious colitis or other suspected or newly diagnosed single or multi-organ immune-mediated disorder or systemic inflammatory reaction

3. (On-Therapy patients only) This patient will continue to receive ZINBRYTA: Yes No
*If no, ZINBRYTA REMS will begin the de-enrollment process for the patient, the patient **will not be eligible to receive ZINBRYTA**, and you will be contacted for patient status information every 90 days for 6 months post-therapy discontinuation.*

ZINBRYTA CERTIFIED PRESCRIBER OR DELEGATE SIGNATURE

Signature	Date
Print name	

Please Note: A ZINBRYTA certified prescriber or delegate may complete and submit this form on behalf of the certified Prescriber of record. The certified Prescriber of record is responsible for compliance with the ZINBRYTA REMS Program requirements, including monitoring, evaluation, and management of each patient under his/her care. If you have questions on this information, please call 1-800-456-2255.