

ZINBRYTA is available only through the ZINBRYTA REMS Program, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the program are able to prescribe, dispense, and receive ZINBRYTA. An authorized representative of the pharmacy must enroll the pharmacy in the ZINBRYTA REMS Program. Fields marked with * are required.



Submit the completed form to the ZINBRYTA REMS Program using the submission details below. ZINBRYTA REMS Program will notify the pharmacy upon successful certification.

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.

New Certification

Recertification With New Authorized Representative (REMS ID #

)

Other Mandatory Field Changes (REMS ID #

)

PHARMACY INFORMATION (PLEASE PRINT)

<input type="text"/>		
Name of Pharmacy*		
<input type="text"/>	<input type="text"/>	<input type="text"/>
NCPDP Number*	NPI Number*	DEA Number*
<input type="text"/>		
Address*		
<input type="text"/>	<input type="text"/>	<input type="text"/>
City*	State*	ZIP*
<input type="text"/>	<input type="text"/>	
Name of Authorized Representative*	Title*	
<input type="text"/>	<input type="text"/>	<input type="text"/>
Phone Number*	Fax Number*	Email Address*

PHARMACY AGREEMENT

I am the authorized representative designated by my Pharmacy to coordinate the activities of the ZINBRYTA REMS Program. By signing this form, I agree, on behalf of myself and Pharmacy, to comply with the following program requirements:

- I will oversee implementation of and ensure my pharmacy's compliance with the ZINBRYTA REMS Program requirements.
- I have reviewed the ZINBRYTA REMS Program Overview and will ensure that all relevant staff involved in the dispensing of ZINBRYTA are trained on the ZINBRYTA REMS Program requirements (as described in the ZINBRYTA REMS Program Overview) and that a record of training is maintained.
- I understand that upon completing the certification requirements and signing this ZINBRYTA REMS Program Pharmacy Enrollment Form, this pharmacy will be enrolled in the ZINBRYTA REMS Program, upon confirmation from the ZINBRYTA REMS Program. I understand that my pharmacy will only dispense ZINBRYTA if certified by the ZINBRYTA REMS Program.
- I will ensure that prior to dispensing ZINBRYTA, my pharmacy will verify that the prescriber is certified and the patient is authorized to receive ZINBRYTA by contacting the ZINBRYTA REMS Program.

- This pharmacy will ensure that no more than a one month supply of ZINBRYTA is dispensed.
- This pharmacy will ensure any adverse events suggestive of hepatic injury or immune-mediated disorders are reported by Pharmacy to the ZINBRYTA REMS Program.
- This pharmacy will maintain and make available appropriate documentation reflecting that all processes and procedures are in place and are being followed for the ZINBRYTA REMS Program and provide copies of such documentation (including, without limitation, patient-specific information), upon request to Biogen, FDA, or any third party acting on behalf of Biogen or FDA.
- This pharmacy will comply with audits by Biogen, FDA, or a third party acting on behalf of Biogen or FDA to ensure compliance with the ZINBRYTA REMS Program.
- This pharmacy will confirm the authorized representative annually and must recertify in the ZINBRYTA REMS Program if there is a personnel change for that authorized representative.
- I understand that non-compliance with the requirements of the ZINBRYTA REMS Program will result in decertification of my Pharmacy and termination of the authorization to dispense ZINBRYTA.

AUTHORIZED REPRESENTATIVE SIGNATURE

<input type="text"/>	<input type="text"/>
Authorized Representative Signature	Date
<input type="text"/>	
Print Name	