

ZINBRYTA REMS (Risk Evaluation and Mitigation Strategy) Program Overview

This overview describes the requirements of the ZINBRYTA REMS Program and the responsibilities of prescribers, pharmacies and patients.

If you have any questions regarding the ZINBRYTA REMS Program, please visit www.zinbrytarems.com or call: **1-800-456-2255**.

Please see Prescribing Information, including BOXED WARNING, for additional Important Safety Information.

Reference ID: 4175674

 **Zinbryta**[®]
(daclizumab)
150 mg Subcutaneous Injection



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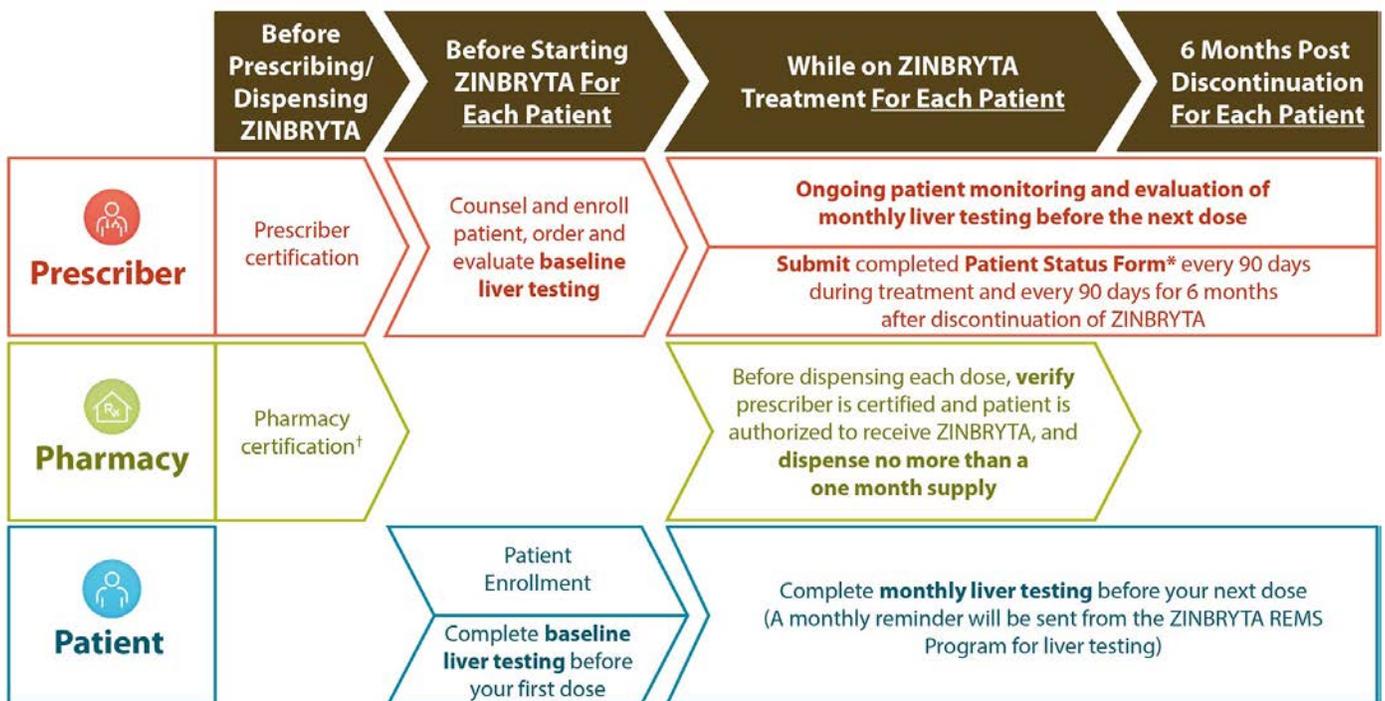
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What is the ZINBRYTA REMS Program?

- A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug continue to outweigh its risks.
- Due to the risks of severe and fatal liver injury, including autoimmune hepatitis and liver failure, and other immune-mediated disorders such as skin reactions, lymphadenopathy, immune-mediated colitis, and other serious conditions, ZINBRYTA is available only through a restricted program called the ZINBRYTA REMS Program.

How Does the ZINBRYTA REMS Program Work?



* Every 90 days during treatment and every 90 days for 6 months after discontinuation of ZINBRYTA, the ZINBRYTA REMS Program will send an individualized Patient Status Form to the certified prescriber for completion.

[†] Recertify if there is a change in authorized representative.



What are the Requirements of the ZINBRYTA REMS Program?

- In order to receive ZINBRYTA, prescribers, patients, and pharmacies must comply with the requirements of the ZINBRYTA REMS Program.

Prescribers



To prescribe ZINBRYTA:

- Become certified** by completing a one-time certification process
- As you start patients on ZINBRYTA, **counsel and enroll** them into the ZINBRYTA REMS Program, complete the prescription, and order and evaluate baseline liver testing
- Perform** ongoing patient monitoring, evaluate **monthly liver testing** prior to each patient's next dose, and complete the ZINBRYTA REMS Program Patient Status Forms for each patient every 90 days during treatment and every 90 days for 6 months after discontinuation of ZINBRYTA

Pharmacies



To dispense ZINBRYTA*:

- Designate an authorized representative, become certified, and recertify** if there is a change in the authorized representative
- Train** staff and **comply** with REMS requirements
- Before dispensing each dose, **verify** prescriber is certified and patient is authorized to receive ZINBRYTA, and **dispense no more than a one month supply**

Patients



To receive ZINBRYTA:

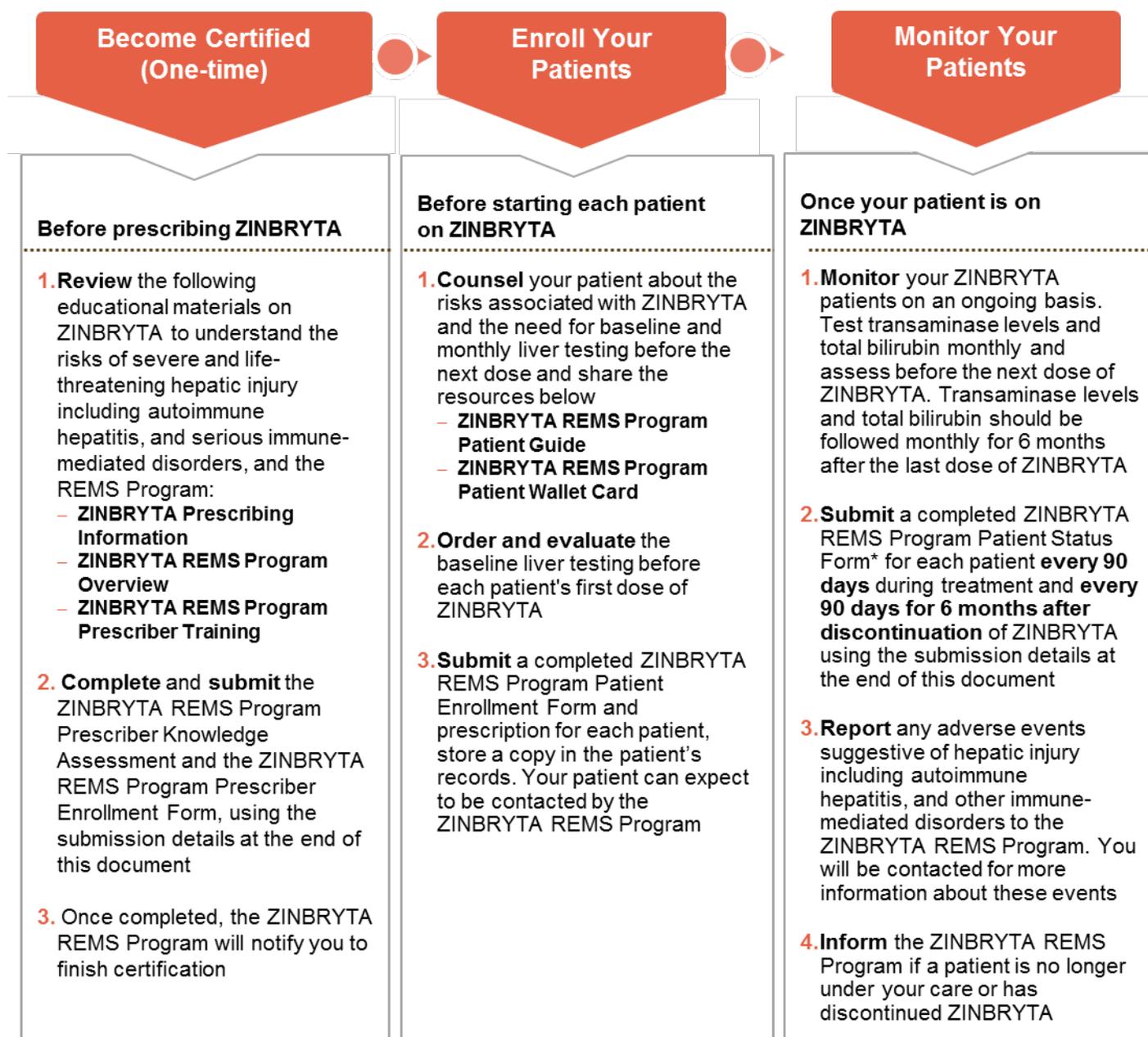
- Understand the risks** associated with ZINBRYTA
- Enroll** in the ZINBRYTA REMS Program by completing the ZINBRYTA REMS Program Patient Enrollment Form with your doctor
- Complete** baseline liver testing before your first dose and monthly liver testing before your next dose of ZINBRYTA. A monthly reminder will be sent from the ZINBRYTA REMS Program for liver testing

* ZINBRYTA is not available to all pharmacies. If you have any questions about the ZINBRYTA REMS Program or how to obtain ZINBRYTA, call 1-800-456-2255.

Prescribers and pharmacies must report any adverse events suggestive of hepatic injury and immune-mediated disorders to the ZINBRYTA REMS Program.



Prescriber Requirements



* Every 90 days during treatment and every 90 days for 6 months after discontinuation of ZINBRYTA, the ZINBRYTA REMS Program will send an individualized Patient Status Form to the certified prescriber for completion.

The completed forms should be submitted to the ZINBRYTA REMS Program online, using the ZINBRYTA Program Portal at www.zinbrytarems.com, via fax to 1-855-474-3067, or by mail to 5000 Davis Drive, PO Box 13919, Research Triangle Park, NC 27709.



Pharmacy Requirements

Become Certified

Before dispensing ZINBRYTA

1. **Designate** an authorized representative for the pharmacy. He or she will need to review the ZINBRYTA REMS Program Overview and will oversee implementation and ensure compliance with the ZINBRYTA REMS Program requirements
2. **Have the authorized representative complete and submit** the ZINBRYTA REMS Pharmacy Enrollment Form using the submission details at the end of this document
 - Once this step is completed, the ZINBRYTA REMS Program will contact you to complete certification
3. **Have the authorized representative ensure** that all relevant staff involved in the dispensing of ZINBRYTA are trained on the ZINBRYTA REMS Program requirements and that a record of training is maintained by the pharmacy

Ensure Compliance With REMS Requirements

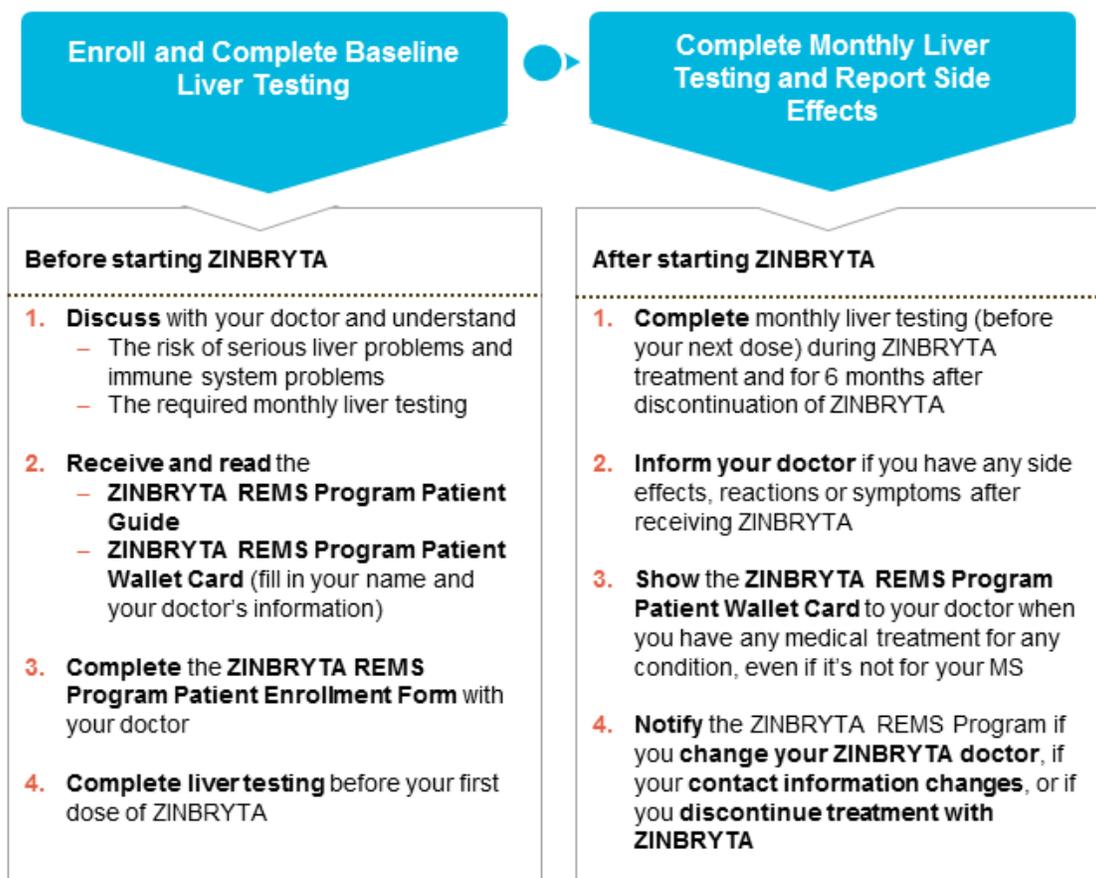
When dispensing ZINBRYTA

1. Before dispensing each dose, **verify** that the prescriber is certified and the patient is authorized to receive ZINBRYTA by calling the ZINBRYTA REMS Program. **Do not dispense more than a one month supply per patient**
2. **Report** any adverse events suggestive of hepatic injury including autoimmune hepatitis, and other immune-mediated disorders to the ZINBRYTA REMS Program. You may be contacted for more information about these events
3. **Maintain** appropriate documentation that all processes and procedures are in place and are being followed so that it can be provided upon request to Biogen, the FDA, or a third party acting on behalf of Biogen or the FDA
4. **Recertify** in the ZINBRYTA REMS Program if a new authorized representative is designated by completing and submitting the ZINBRYTA REMS Pharmacy Enrollment Form

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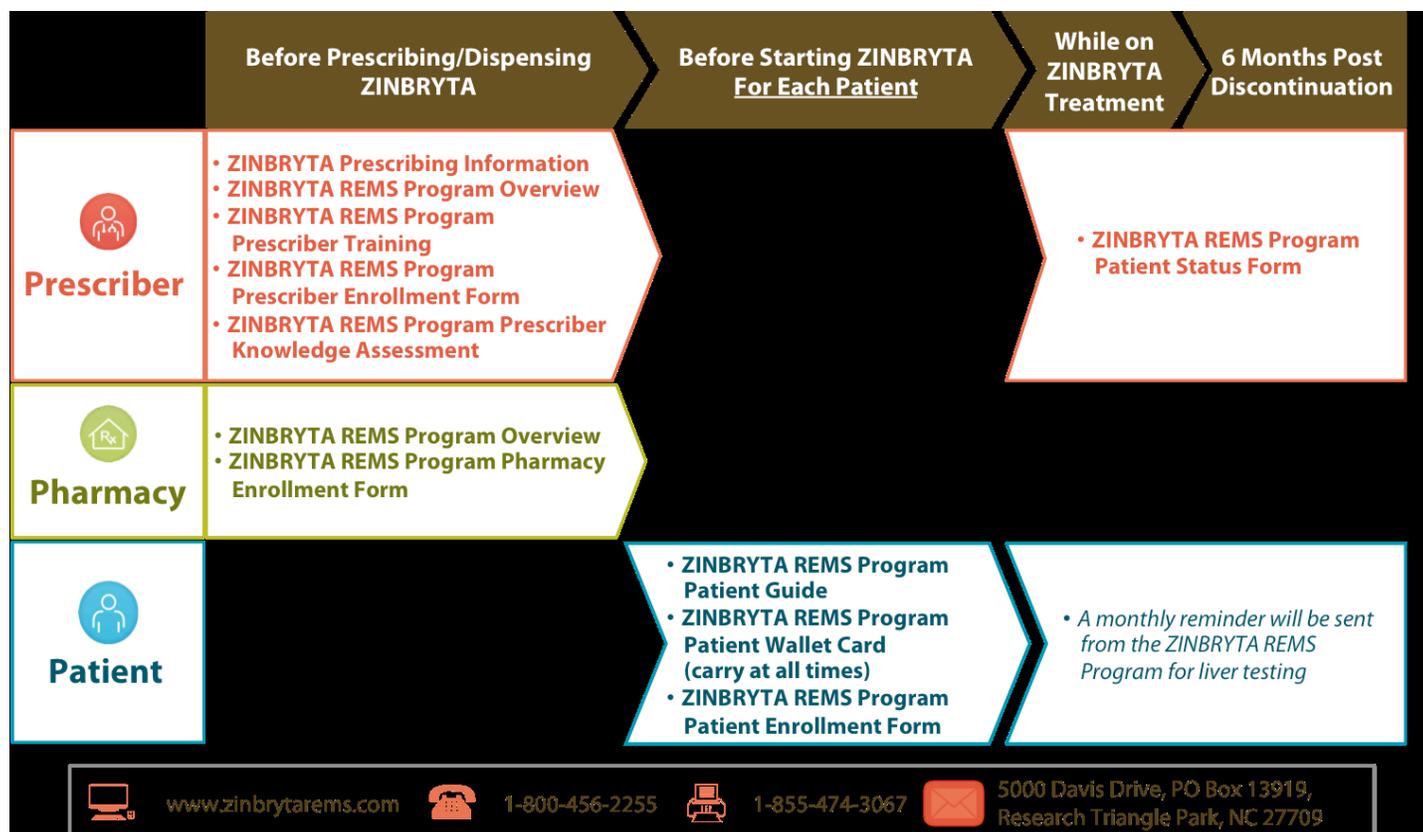


Patient Requirements





ZINBRYTA REMS Program Resources



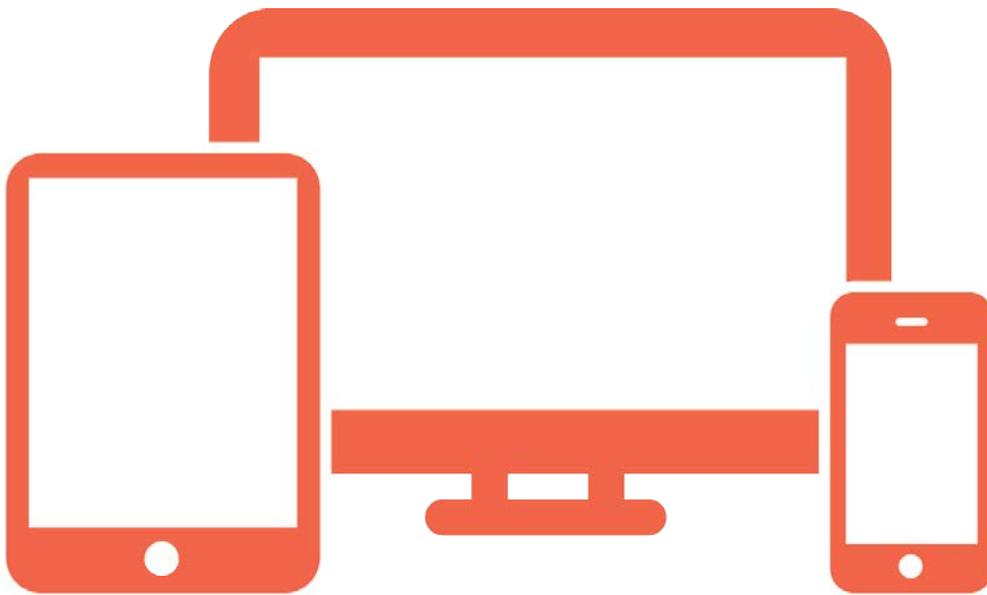
ZINBRYTA is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of ZINBRYTA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Please see Prescribing Information, including BOXED WARNING, for additional Important Safety Information.



ZINBRYTA Program Portal Overview

- ZINBRYTA Program Portal is a web-based tool designed to:
 - Provide real-time access to ZINBRYTA patient data
 - Maintain compliance with the ZINBRYTA REMS Program
 - Streamline communication to/from prescribers
- ZINBRYTA Program Portal is now available for prescribers to instantly enroll, train, certify, and manage their patients online
- ZINBRYTA Program Portal is accessed with secure user name and password





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