For Patients

ZINBRYTA REMS (Risk Evaluation and Mitigation Strategy) Program Patient Guide

Patients: Your doctor will go over this patient guide with you. It is important to ask any questions you might have. Keep this guide for important safety information about the serious risks of ZINBRYTA.

Healthcare Providers: Review this patient guide with your patient, and provide your patient a copy to take home.

To learn more about ZINBRYTA, please talk to your doctor and visit **www.zinbrytarems.com**. You can also call us at **1-800-456-2255.**

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(daclizumab)
150 mg Subcutaneous Injection

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What is ZINBRYTA?

ZINBRYTA is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS). Because of its risks, ZINBRYTA is generally used in people who have tried 2 or more MS medicines that have not worked well enough.

What are the most serious risks of ZINBRYTA?

ZINBRYTA can cause serious liver problems (including autoimmune-related liver problems) that may lead to death. It can also cause other immune system problems. **Contact your doctor right away and seek emergency medical care if you have any of the following symptoms:**

Liver problems. Symptoms include:

- Nausea or vomiting
- Stomach pain
- Unusual tiredness
- Not wanting to eat
- Yellowing of the skin or whites of your eyes
- Dark urine

Immune system problems. Some people using ZINBRYTA develop immune mediated disorders (a condition where the body's immune cells attack other cells or organs in the body) and other immune system problems. Symptoms include:

- Skin reactions such as rash or skin irritation
- Tender, painful, or swollen lymph nodes
- Symptoms of low red blood cell counts which can include looking very pale, feeling more tired than usual, dark urine, shortness of breath, or yellowing of the skin or whites of your eyes
- Intestinal problems (colitis). Symptoms can include fever, stomach pain, blood in your stools, or diarrhea that does not go away
- Any new and unexplained symptoms affecting any part of your body

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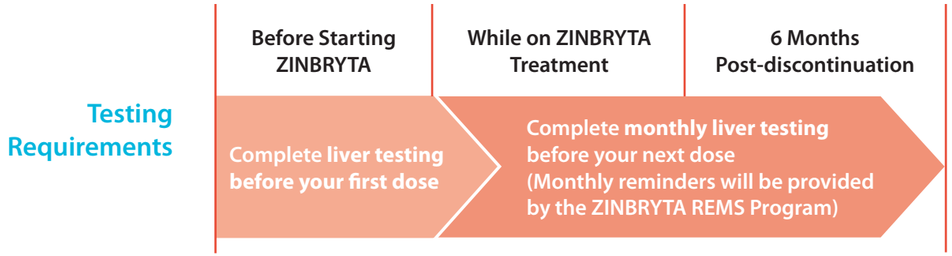
What is the ZINBRYTA REMS Program?

- 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.
- Because of the risk of serious liver problems (including autoimmune-related liver problems) and other immune system problems, ZINBRYTA is only available through a restricted program called the ZINBRYTA Risk Evaluation and Mitigation (REMS) Program.
- The ZINBRYTA REMS Program educates patients and doctors about these risks associated with ZINBRYTA.
- Requirements of the ZINBRYTA REMS Program include the following:
  - You and your doctor must be enrolled in the ZINBRYTA REMS Program in order to receive and prescribe ZINBRYTA.
  - ZINBRYTA is only available from pharmacies that participate in the ZINBRYTA REMS Program.
- Your doctor will do blood tests to check your liver before you start using ZINBRYTA, every month while you are using ZINBRYTA, and for 6 months after you stop using ZINBRYTA. Your doctor will check your test results before your next dose.



It is very important that you complete these monthly blood tests to check your liver, even if you are feeling well.

How do I enroll in the ZINBRYTA REMS Program and what is required of me?

Before starting ZINBRYTA:

☑ **Discuss** with your doctor and understand:
- The risk of serious liver problems and immune system problems.
- The required monthly liver testing.

☑ **Receive and read:**
- This **ZINBRYTA REMS Program Patient Guide**.
- The **ZINBRYTA REMS Program Patient Wallet Card** (fill in your name and your doctor's information).

☑ **Complete** the **ZINBRYTA REMS Program Patient Enrollment Form** with your doctor.

☑ **Complete liver testing** before your first dose of ZINBRYTA.

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How do I enroll in the ZINBRYTA REMS Program and what is required of me? (cont'd)

Your doctor will help you fill out the ZINBRYTA REMS Program Patient Enrollment Form mentioned on the previous page. You will be asked to acknowledge the following:

- I have received, read, and understand the ZINBRYTA REMS Program Patient Guide that my doctor has given me.
- In order to receive ZINBRYTA, I am required to enroll in the ZINBRYTA REMS Program, and my information will be stored in a secure database of all patients who receive ZINBRYTA in the United States. After enrolling, my doctor will provide me with a signed copy of this enrollment form.
- ZINBRYTA can cause serious side effects. It can cause serious liver problems (including autoimmune-related liver problems) that may lead to death. ZINBRYTA can also cause other immune system problems. These complications can be identified through monthly testing and awareness of side effects, reactions, or symptoms. My doctor has reviewed with me the risks of treatment with ZINBRYTA.
- I must complete liver testing before my first dose of ZINBRYTA, every month (before my next dose) during ZINBRYTA treatment, and for 6 months after discontinuation of ZINBRYTA. It is important that I complete these monthly blood tests to check my liver, even if I am feeling well.
- I will not be able to receive ZINBRYTA if I do not complete the required monthly liver testing.
- I will tell my doctor if I have any side effects, reactions, or symptoms after receiving ZINBRYTA.
- My doctor has counseled and given me the ZINBRYTA REMS Program Patient Wallet Card, which I will carry with me at all times. I will show this card to all my doctors involved in my medical treatment, even if it is not for my MS.
- I will tell all of my doctors that I have been treated with ZINBRYTA.
- I will tell the ZINBRYTA REMS Program right away if I change my ZINBRYTA doctor, if my contact information changes, or if I discontinue ZINBRYTA.
- I give permission to Biogen and its agents to use and share my personal health information for the purposes of enrolling me into and administering the ZINBRYTA REMS Program, coordinating the dispensing of ZINBRYTA, and releasing my personal health information to the Food and Drug Administration (FDA), as necessary.
- Biogen and its agents may contact me via phone, mail, or email to support administration of the ZINBRYTA REMS Program.

After enrolling, what are the next steps? And how will I receive ZINBRYTA?

Upon enrollment:

1. A Biogen representative from the ZINBRYTA REMS Program will contact you to get you started.
2. The pharmacy will call you to schedule a shipment of ZINBRYTA that will come right to your home.
   - ZINBRYTA is only available from pharmacies that participate in the ZINBRYTA REMS Program.
   - The pharmacy will dispense only a one month supply at a time.
3. Once you start taking ZINBRYTA, it will be important for you to complete your liver testing every month before your next dose.

After starting ZINBRYTA:

☑ **Complete** monthly liver testing (before your next dose) during ZINBRYTA treatment and for 6 months after discontinuation.

☑ **Inform your doctor** if you have any side effects, reactions or symptoms after receiving ZINBRYTA.

☑ **Show** the **ZINBRYTA REMS Program Patient Wallet Card** to your doctor when you have any medical treatment, even if it is not for your MS.

☑ **Notify** the ZINBRYTA REMS Program if you **change your ZINBRYTA doctor**, if your **contact information changes**, or if you **discontinue treatment with ZINBRYTA.**

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If you have any questions regarding the ZINBRYTA REMS Program,
visit www.zinbrytarems.com or call: **1-800-456-2255**
Fax: **1-855-474-3067**
Mail: **5000 Davis Drive, PO Box 13919, Research Triangle Park, NC 27709**

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