



ZINBRYTA REMS Program

What is the ZINBRYTA (daclizumab) Risk Evaluation and Mitigation Strategy (REMS) Program?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug 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.**

Prescribers



Click here to learn how to prescribe ZINBRYTA:

1. **Become certified** by completing a one-time certification process
2. 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
3. **Perform** ongoing patient monitoring, evaluate **monthly liver testing before 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



Click here to learn how to dispense ZINBRYTA:

1. **Designate an authorized representative, become certified, and recertify** if there is a change in the authorized representative
2. **Train** staff and **comply** with REMS requirements
3. 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



Click here to learn how to receive ZINBRYTA:

1. **Understand the risks** associated with ZINBRYTA
2. **Enroll** in the ZINBRYTA REMS Program by completing the ZINBRYTA REMS Program Patient Enrollment Form with your doctor
3. **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 need help enrolling, call **1-800-456-2255.*

Indication

ZINBRYTA is indicated for the treatment of adult 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 information.

Prescribing Information Instructions for Use Medication Guide

Zinbryta[®]
(daclizumab)
150mg Subcutaneous Injection

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ZINBRYTA REMS Program: For Prescribers - Available Online

Prescribers

Prescribers are now able to use the ZINBRYTA Program Portal to instantly enroll, train, certify, and manage their patients all online. If you are already a certified ZINBRYTA REMS Program prescriber, click **Create Account**. If you need to become certified, click **Enroll Here**.

Already Certified?
Create an online account to manage ZINBRYTA patients
Create Account

Begin Certification
Create an online account and become ZINBRYTA REMS Program certified
Enroll Here

To enroll in the ZINBRYTA REMS Program via fax or mail, [click here](#) for the required forms.

The requirements for treating with ZINBRYTA (daclizumab)

Please complete this **3-step process** to prescribe ZINBRYTA.

Step 1. Become certified:

Complete the certification process before you prescribe ZINBRYTA >

Step 2. Before you start your patients on ZINBRYTA:

Enroll the patient in the ZINBRYTA REMS Program >

Step 3. Once a patient starts on ZINBRYTA:

Perform monthly monitoring and evaluation >

*If you have any questions about the ZINBRYTA REMS Program or need help enrolling, call **1-800-456-2255**.*

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Already Certified?
Create an online account to manage ZINBRYTA patients

[Create Account](#)

Begin Certification
Create an online account and become ZINBRYTA REMS Program certified

[Enroll Here](#)

To enroll in the ZINBRYTA REMS Program via fax or mail, [click here](#) for the required forms.

The requirements for treating with ZINBRYTA (daclizumab)

Please complete this 3-step process to prescribe ZINBRYTA.

Step 1. Become certified:

Complete the certification process before you prescribe ZINBRYTA

1. **Register** online to create a prescriber account and to access the ZINBRYTA Program Portal.

2. **Review** the following educational materials on ZINBRYTA to understand the risks of severe and fatal liver injury, including autoimmune hepatitis and liver failure, and serious immune-mediated disorders, and the ZINBRYTA REMS Program. Download the:



ZINBRYTA Prescribing Information



ZINBRYTA REMS Program Overview



ZINBRYTA REMS Program Prescriber Training

3. **Complete** the ZINBRYTA REMS Program Prescriber Knowledge Assessment and the ZINBRYTA REMS Program Prescriber Enrollment Form online, using the [ZINBRYTA Program Portal](#), or via paper. You must answer all questions in the ZINBRYTA REMS Program Prescriber Knowledge Assessment correctly to become certified. Download the:



ZINBRYTA REMS Program Prescriber Knowledge Assessment



ZINBRYTA REMS Program Prescriber Enrollment Form

4. **Submit** the ZINBRYTA REMS Program Prescriber Knowledge Assessment and the ZINBRYTA REMS Program Prescriber Enrollment Form online, using the [ZINBRYTA Program Portal](#). Alternatively, the completed forms may also be faxed to the ZINBRYTA REMS Program at 1-855-474-3067, or mailed to the ZINBRYTA REMS Program at 5000 Davis Drive, PO Box 13919, Research Triangle Park, NC 27709. You will be notified by the ZINBRYTA REMS Program within 2 business days upon receipt. When notified, you will receive either:

- A confirmation of your certification in the ZINBRYTA REMS Program

OR

- If necessary, instructions on how to retake the ZINBRYTA REMS Program Prescriber Knowledge Assessment

Once this one-time step has been completed, the ZINBRYTA REMS Program will contact you to finish certification.

Step 2. Before you start your patients on ZINBRYTA:

Enroll the patient in the ZINBRYTA REMS Program

1. **Counsel** your patient about the risks associated with ZINBRYTA and the need for baseline and monthly liver testing before the next dose and share the resources provided below. Download the:



ZINBRYTA REMS Program Patient Guide



ZINBRYTA REMS Program Patient Wallet Card

2. **Order and evaluate** the baseline liver testing before each patient's first dose of ZINBRYTA.

3. **Complete** the ZINBRYTA REMS Program Patient Enrollment Form and prescription with your patient online, using the [ZINBRYTA Program Portal](#), or via paper and provide them with a copy of the finished form. Download the:



ZINBRYTA REMS Program Patient Enrollment Form

4. **Submit** the completed ZINBRYTA REMS Program Patient Enrollment Form online, using the [ZINBRYTA Program Portal](#), and store a copy in the patient's record. Completed forms can also be faxed to the ZINBRYTA REMS Program at 1-855-474-3067, or mailed to the ZINBRYTA REMS Program at 5000 Davis Drive, PO Box 13919, Research Triangle Park, NC 27709. Your patient can expect to be contacted by the ZINBRYTA REMS Program.

Step 3. Once a patient starts on ZINBRYTA:

Perform monthly monitoring and evaluation

1. **Monitor** your ZINBRYTA patients on an ongoing basis. Test transaminase levels and total bilirubin monthly and assess before the next dose of ZINBRYTA. Transaminase levels and total bilirubin should be followed monthly for 6 months after the last dose of ZINBRYTA. The patient will be contacted by the ZINBRYTA REMS Program each month to remind them to complete their liver testing.

If there are changes in the test results, adjust the monitoring and treatment with ZINBRYTA as follows:

Lab values	Recommendations
ALT or AST >5x ULN OR Total bilirubin >2x ULN OR ALT or AST ≥3 but <5x ULN and total bilirubin >1.5 but <2x ULN	Interrupt ZINBRYTA therapy and investigate for other etiologies of abnormal lab values If no other etiologies are identified, then discontinue ZINBRYTA If other etiologies are identified, re-assess the overall risk-benefit profile of ZINBRYTA in the patient and consider whether to resume ZINBRYTA when both AST or ALT are <2x ULN and total bilirubin is ≤ to ULN*

*In clinical trials, permanent discontinuation of therapy was required if the patient had liver test abnormalities resulting in suspension of study treatment for at least 8 consecutive weeks.
ALT=alanine aminotransferase; AST=aspartate aminotransferase; ULN=upper limit of normal.

2. **Submit** a completed ZINBRYTA REMS Program Patient Status Form online, using the [ZINBRYTA Program Portal](#) or send a completed form via fax or mail, **every 90 days** during treatment and **every 90 days for 6 months after discontinuation** of ZINBRYTA. Every 90 days, the ZINBRYTA REMS Program will send an individualized Patient Status Form to the certified prescriber for completion. Download the:



ZINBRYTA REMS Program Patient Status Form

3. **Report** any adverse events suggestive of hepatic injury including autoimmune hepatitis, and other immune-mediated disorders to the ZINBRYTA REMS Program at 1-800-456-2255. You will be contacted for more information about these events.

4. **Inform** the ZINBRYTA REMS Program if the patient is no longer under your care or has discontinued ZINBRYTA.

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If you have any questions about the ZINBRYTA REMS Program or need help enrolling, call 1-800-456-2255.

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(daclizumab)
150mg Subcutaneous Injection

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ZINBRYTA REMS Program: For Pharmacies

Pharmacies

 The requirements for dispensing ZINBRYTA (daclizumab)

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**.

Please complete this **2-step process** to dispense ZINBRYTA.

Step 1. Become certified:

Complete the certification process before you are authorized to dispense ZINBRYTA [>](#)

Step 2. Dispense ZINBRYTA to authorized patients:

Ensure compliance with the ZINBRYTA REMS Program requirements [>](#)

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*If you have any questions about the ZINBRYTA REMS Program
or need help enrolling, call **1-800-456-2255**.*

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ZINBRYTA REMS Program: For Pharmacies

Pharmacies

The requirements for dispensing ZINBRYTA (daclizumab)
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.

Please complete this **2-step process** to dispense ZINBRYTA.

Step 1. Become certified:

Complete the certification process before you are authorized to dispense ZINBRYTA

- 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. Download the:
 [ZINBRYTA REMS Program Overview](#)
- Have the authorized representative complete** the ZINBRYTA REMS Program Pharmacy Enrollment Form. Download the:
 [ZINBRYTA REMS Program Pharmacy Enrollment Form](#)
- Submit** the completed form to the ZINBRYTA REMS Program. Completed forms should be faxed to the ZINBRYTA REMS Program at **1-855-474-3067**, or mailed to the ZINBRYTA REMS Program at **5000 Davis Drive, PO Box 13919, Research Triangle Park, NC 27709**. You will be contacted by the ZINBRYTA REMS Program to complete certification.
- 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.

Step 2. Dispense ZINBRYTA to authorized patients:

Ensure compliance with the ZINBRYTA REMS Program requirements

- Before dispensing each dose, **verify** that the prescriber is certified and the patient is authorized to receive ZINBRYTA by calling the ZINBRYTA REMS Program at **1-800-456-2255**. **Do not dispense more than a one month supply per patient.**
- Ensure** that the pharmacy complies with the procedures required by the ZINBRYTA REMS Program:
 - Report** any adverse events suggestive of hepatic injury including autoimmune hepatitis, and other immune-mediated disorders to the ZINBRYTA REMS Program at **1-800-456-2255**. You may be contacted for more information about these events.
 - 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.
 - Comply** with potential audits conducted by Biogen, FDA, or a third party acting on behalf of Biogen or the FDA to ensure that all processes and procedures are in place and are being followed.
- Recertify** in the ZINBRYTA REMS Program if a new authorized representative is designated by completing and submitting the ZINBRYTA REMS Program Pharmacy Enrollment Form.

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free [here](#).

If you have any questions about the ZINBRYTA REMS Program or need help enrolling, call 1-800-456-2255.

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ZINBRYTA REMS Program: For Patients

Patients

The requirements for receiving treatment with ZINBRYTA (daclizumab)
Work with your doctor to complete this **2-step process** so you can start treatment on ZINBRYTA.

Step 1. Complete enrollment:

Enroll, understand the risks, and complete liver testing before starting treatment [>](#)

Step 2. Continue treating your relapsing MS:

Complete monthly liver testing before your next dose and report side effects [>](#)

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*If you have any questions about the ZINBRYTA REMS Program
or need help enrolling, call **1-800-456-2255**.*

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ZINBRYTA REMS Program: For Patients



The requirements for receiving treatment with ZINBRYTA (daclizumab)

Work with your doctor to complete this 2-step process so you can start treatment on ZINBRYTA.

Step 1. Complete enrollment:

Enroll, understand the risks, and complete liver testing before starting treatment

1. Discuss the following with your doctor and make sure you understand:

- The risks of ZINBRYTA including serious liver problems that may lead to death and immune system problems.
- The baseline liver testing required before your first dose and monthly liver testing required before your next dose.

2. Receive and read the ZINBRYTA REMS Program Patient Guide and the ZINBRYTA REMS Program Patient Wallet Card.

- The ZINBRYTA REMS Program Patient Guide is your comprehensive guide to understanding treatment with ZINBRYTA.
- The ZINBRYTA REMS Program Patient Wallet Card, which is provided for you to carry during treatment and for up to 6 months after stopping treatment, can be shared with your other doctors.

Download the:



ZINBRYTA REMS Program Patient Guide



ZINBRYTA REMS Program Patient Wallet Card

3. Complete the ZINBRYTA REMS Program Patient Enrollment Form with your doctor who will provide you with a copy of this form. You can expect to be contacted by the ZINBRYTA REMS Program.

4. Complete baseline liver testing before your first dose to ensure ZINBRYTA is safe for you to use, as guided by your doctor. You can expect to be contacted by the ZINBRYTA REMS Program each month to remind you to complete your lab tests.

Step 2. Continue treating your relapsing MS:

Complete monthly liver testing before your next dose and report side effects

1. Complete your monthly liver testing before your next dose during treatment with ZINBRYTA and for 6 months after you discontinue treatment with ZINBRYTA.

2. Inform your doctor of any side effects, reactions, or symptoms you experience after receiving ZINBRYTA.

3. Carry your ZINBRYTA REMS Program Patient Wallet Card and tell any of your other doctors that you have been treated with ZINBRYTA.

4. Notify the ZINBRYTA REMS Program right away if you change your ZINBRYTA doctor, if your contact information changes, or if you discontinue treatment with ZINBRYTA.

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free [here](#).

If you have any questions about the ZINBRYTA REMS Program or need help enrolling, call 1-800-456-2255.

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ZINBRYTA REMS Program: Forms and Resources

Below are downloadable forms required to become certified and enrolled in the ZINBRYTA (daclizumab) REMS Program.



Materials for Prescribers

[Click here](#) to learn more about these resources. Download the:

Prescriber Education and Certification

- ZINBRYTA Prescribing Information
- ZINBRYTA REMS Program Overview
- ZINBRYTA REMS Program Prescriber Training
- ZINBRYTA REMS Program Prescriber Knowledge Assessment
- ZINBRYTA REMS Program Prescriber Enrollment Form
- ZINBRYTA REMS Program Letter for Healthcare Providers

Patient Enrollment

- ZINBRYTA REMS Program Patient Enrollment Form

Continuing Enrolled Patients on Treatment

- ZINBRYTA REMS Program Patient Status Form



Materials for Pharmacies

[Click here](#) to learn more about these resources. Download the:

- ZINBRYTA REMS Program Overview
- ZINBRYTA REMS Program Pharmacy Enrollment Form



Materials for Patient Counseling

[Click here](#) to learn more about these resources. Download the:

- ZINBRYTA REMS Program Patient Guide
- ZINBRYTA REMS Program Patient Wallet Card

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5000 Davis Drive
PO Box 13919
Research Triangle Park, NC 27709
Phone: 1-800-456-2255
Fax: 1-855-474-3067

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100mg Intravenous Injection

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ZINBRYTA REMS Program

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1. Become certified by completing a one-time certification process.
2. 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.
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Pharmacies:

1. Designate an authorized representative, become certified, and recertify if there is a change in the authorized representative.
2. Train staff and comply with REMS requirements.
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/s/

ALICE HUGHES
11/01/2017