



# ZINBRYTA REMS (Risk Evaluation and Mitigation Strategy) Program Prescriber Training

**This training includes information about:**

- Risks of severe and fatal hepatic injury and serious immune-mediated disorders associated with ZINBRYTA
- Requirements for monthly monitoring and evaluation of your patient
- The ZINBRYTA REMS Program requirements



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The review of this document is necessary to successfully pass the ZINBRYTA REMS Program Prescriber Knowledge Assessment in order to prescribe ZINBRYTA



## What Is ZINBRYTA?

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- 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 Important Safety Information.



## Risks Associated With ZINBRYTA: *Hepatic Injury*

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- **ZINBRYTA can cause severe liver injury, including autoimmune hepatitis and liver failure. Fatal cases have occurred.**
  - Elevations of serum transaminases and severe hepatic injury have occurred in patients treated with ZINBRYTA. Liver injury, including autoimmune hepatitis and acute liver failure, can occur at any time during treatment with ZINBRYTA, with cases reported up to 5 months after the last dose of ZINBRYTA.
  - In controlled studies, an increased incidence of elevations of alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >5 times the upper limit of normal (ULN) was reported in ZINBRYTA-treated patients compared with placebo-treated patients (4% vs 1%) and compared with AVONEX-treated patients (6% vs 3%).
  - Across all clinical studies (controlled and open-label), serious drug-related hepatic injury occurred in 1.7% of ZINBRYTA-treated patients.
  - In a clinical trial, a case of fatal autoimmune hepatitis with acute liver failure occurred in a patient reinitiating treatment with ZINBRYTA after a planned 6-month treatment interruption period.
  - A case of acute liver failure occurred in a patient receiving ZINBRYTA in the postmarketing setting after 4 doses of ZINBRYTA, resulting in transplant and death. The patient was also receiving concomitant treatment with another drug known to be associated with hepatic injury.
  - In the active-controlled study, the incidence of drug discontinuation due to hepatic disorders was 5% in ZINBRYTA-treated patients and 4% in AVONEX-treated patients.



## Risks Associated With ZINBRYTA: *Immune-Mediated Disorders*

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- **Immune-mediated disorders including skin reactions, lymphadenopathy, and immune-mediated colitis can occur in patients treated with ZINBRYTA. Overall, serious immune-mediated disorders were observed in 5% of patients treated with ZINBRYTA.**
  - Treatment with ZINBRYTA can increase the risk of immune-mediated disorders, including autoimmune disorders such as autoimmune hepatitis.
  - Immune-mediated disorders including skin reactions, lymphadenopathy, autoimmune hemolytic anemia, and immune-mediated colitis occurred in patients treated with ZINBRYTA.
  - Additionally, a wide variety of other immune-mediated disorders, some serious, have occurred with the use of ZINBRYTA. These include single organ or systemic multi-organ inflammatory reactions.
  - Overall in clinical trials, immune-mediated disorders occurred in 28% of patients on ZINBRYTA, the most common of which were skin reactions and lymphadenopathy.
  - In the active controlled study, immune-mediated disorders were observed in 32% of ZINBRYTA-treated patients compared with 12% for AVONEX-treated patients.
  - Serious immune-mediated disorders were observed in 4% of patients treated with ZINBRYTA compared with less than 1% for AVONEX-treated patients.
- **Some patients required systemic corticosteroids or other immunosuppressant treatment for autoimmune hepatitis or other immune-mediated disorders and continued this treatment after the last dose of ZINBRYTA.**



## Risks Associated With ZINBRYTA: *Immune-Mediated Disorders*

### 1. Skin Reactions

- In clinical trials, skin reactions occurred in 18% of ZINBRYTA-treated patients compared to 13% of patients on placebo, and in 37% of ZINBRYTA-treated patients compared to 19% of AVONEX-treated patients.
- Skin reactions occurred at any time during treatment with ZINBRYTA.
- The most common skin reactions were dermatitis and eczema.
- Serious skin reactions occurred in 2% of subjects treated with ZINBRYTA and 0.1% of patients on AVONEX. One death resulted from infectious complications following a serious cutaneous reaction. In patients with a history of skin conditions, including eczema or psoriasis, use of ZINBRYTA may exacerbate those conditions.
- In addition to serious cases of dermatitis, eczema, psoriasis and drug eruptions, cases of erythema multiforme, erythema nodosum, exfoliative rash, and oral ulcers occurred in ZINBRYTA clinical trials.
- Treatment of skin reactions included treatment with topical or systemic corticosteroids, or immunosuppressant drugs, including tacrolimus.
- In clinical trials, discontinuation because of skin reactions was 4% in ZINBRYTA-treated patients. Rashes took a mean of 3 months to resolve, some were unresolved at the time of the last evaluation.



## Risks Associated With ZINBRYTA: *Immune-Mediated Disorders*

### 2. Lymphadenopathy

- In clinical trials, ZINBRYTA increased the incidence of lymphadenopathy, with onset occurring throughout the treatment period. In a controlled trial, 6% of ZINBRYTA-treated patients compared to 1% of AVONEX-treated patients developed lymphadenopathy or lymphadenitis.
- Serious events related to lymphadenopathy or lymphadenitis included infections, benign salivary neoplasm, skin reactions, thrombocytopenia, and interstitial lung changes.

### 3. Autoimmune Hemolytic Anemia

- Across all clinical studies (controlled and open-label), autoimmune hemolytic anemia occurred in <1% of patients treated with ZINBRYTA.
- Autoimmune hemolytic anemia resolved with discontinuation of ZINBRYTA, corticosteroid or other immunosuppressant treatment, and blood transfusions in most cases.
- If a patient develops signs or symptoms of autoimmune hemolytic anemia (eg, pallor, fatigue, dark urine, jaundice, shortness of breath), consider discontinuing ZINBRYTA and referring to an appropriate specialist for further evaluation and treatment.



## Risks Associated With ZINBRYTA: *Immune-Mediated Disorders*

### 4. Immune-Mediated Colitis

- An increased incidence of serious colitis (less than 1%) was reported in patients treated with ZINBRYTA compared with placebo and AVONEX in clinical trials.
- Cases have included reports of colitis, ulcerative colitis, Crohn's disease, microscopic colitis, inflammatory bowel disease, proctitis, and proctocolitis.
- Consider discontinuing ZINBRYTA and referring patients who develop symptoms of colitis (eg, abdominal pain, fever, prolonged diarrhea, bloody stools) to a specialist.

### 5. Other Immune-Mediated Disorders

- A wide variety of other immune-mediated disorders, some serious, have occurred with the use of ZINBRYTA. These include single organ or systemic multi-organ inflammatory reactions.
- Some required treatment with systemic corticosteroids or other immunosuppressants. Some required several months for resolution after the last dose of ZINBRYTA, and some had not resolved even several months after discontinuation of ZINBRYTA, at the time of last reported follow-up.



## Additional Risks and Safety Information

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- The information presented in this training program does not include a complete list of all safety information for ZINBRYTA.
- To review the complete safety information on ZINBRYTA, please refer to the Prescribing Information, including BOXED WARNING, for ZINBRYTA at [www.zinbrytarems.com](http://www.zinbrytarems.com).



# Clinical Considerations and Assessment



## Assessment Prior to Initiating ZINBRYTA

### Baseline Tests Required

- Early identification of elevated liver enzymes may decrease the risk of a serious outcome. Prior to starting ZINBRYTA, obtain and evaluate serum transaminases (ALT and AST) and total bilirubin levels.

### Contraindications

ZINBRYTA is contraindicated for patients with:

- Pre-existing hepatic disease or hepatic impairment, including ALT or AST at least 2 times the ULN, because ZINBRYTA could exacerbate existing liver dysfunction.
- A history of autoimmune hepatitis or other autoimmune condition involving the liver.
- A history of hypersensitivity to daclizumab or any other components of the formulation. Use in such patients may result in anaphylaxis or life-threatening multi-organ hypersensitivity.

ULN=upper limit of normal.



## Upon Initiation of ZINBRYTA: *Monitoring for Hepatic Injury*

### Ongoing Tests Required

- Testing of serum transaminase (ALT and AST) levels and total bilirubin should be done monthly and assessed before the next dose of ZINBRYTA. Transaminase levels and total bilirubin should be followed monthly for 6 months after the last dose of ZINBRYTA.
- In case of elevation in transaminases or total bilirubin, treatment interruption or discontinuation may be required.

### Evaluating Monthly Lab Tests

#### Lab values

ALT or AST >5x ULN  
**OR**  
Total bilirubin >2x ULN  
**OR**  
ALT or AST  $\geq 3$  but <5x ULN and total bilirubin >1.5 but <2x ULN

#### Recommendations

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  $\leq$  ULN\*

### Monitoring and Evaluation

- Liver failure can occur at any time during treatment with ZINBRYTA even with monthly liver enzyme monitoring indicating normal values prior to each dose. Liver injury has been reported up to 5 months after the last dose of ZINBRYTA.
- Monitor patients for signs and symptoms of hepatic injury. If a patient develops clinical signs or symptoms suggestive of hepatic dysfunction (eg, unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine), promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with ZINBRYTA, as appropriate.
- In patients with prolonged elevations of serum transaminases, evaluate for other possible causes, such as infection, and a specialist should evaluate the patient.
- Discontinue ZINBRYTA if autoimmune hepatitis is suspected. Treatment of autoimmune hepatitis with systemic corticosteroids and other immunosuppressant drugs may be required. Some patients may need long-term immunosuppression.

\* 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.  
ULN=upper limit of normal.



## Upon Initiation of ZINBRYTA: *Monitoring for Immune-Mediated Disorders*

### Monitoring and Evaluation

- For suspected immune-mediated disorders, ensure adequate evaluation to confirm etiology or to exclude other causes.
- Monitor for signs and symptoms such as fever, a serious diffuse or inflammatory rash, lymphadenopathy, signs or symptoms of autoimmune hemolytic anemia (eg, pallor, fatigue, dark urine, jaundice, shortness of breath), symptoms of colitis (eg, abdominal pain, fever, prolonged diarrhea, bloody stools) and other organ-specific symptoms.
- Some patients required invasive procedures for diagnosis (eg, colonoscopy, liver biopsy, kidney biopsy, lung biopsy), hospitalization for fluid replacement or blood transfusion, or prolonged treatment with systemic corticosteroids or immunosuppressant drugs. Some of these events did not resolve after stopping ZINBRYTA during study follow-up.
- If a patient develops a serious immune-mediated disorder consider stopping ZINBRYTA and refer the patient to a specialist to ensure comprehensive diagnostic evaluation and appropriate treatment.



# Introduction to the ZINBRYTA REMS Program



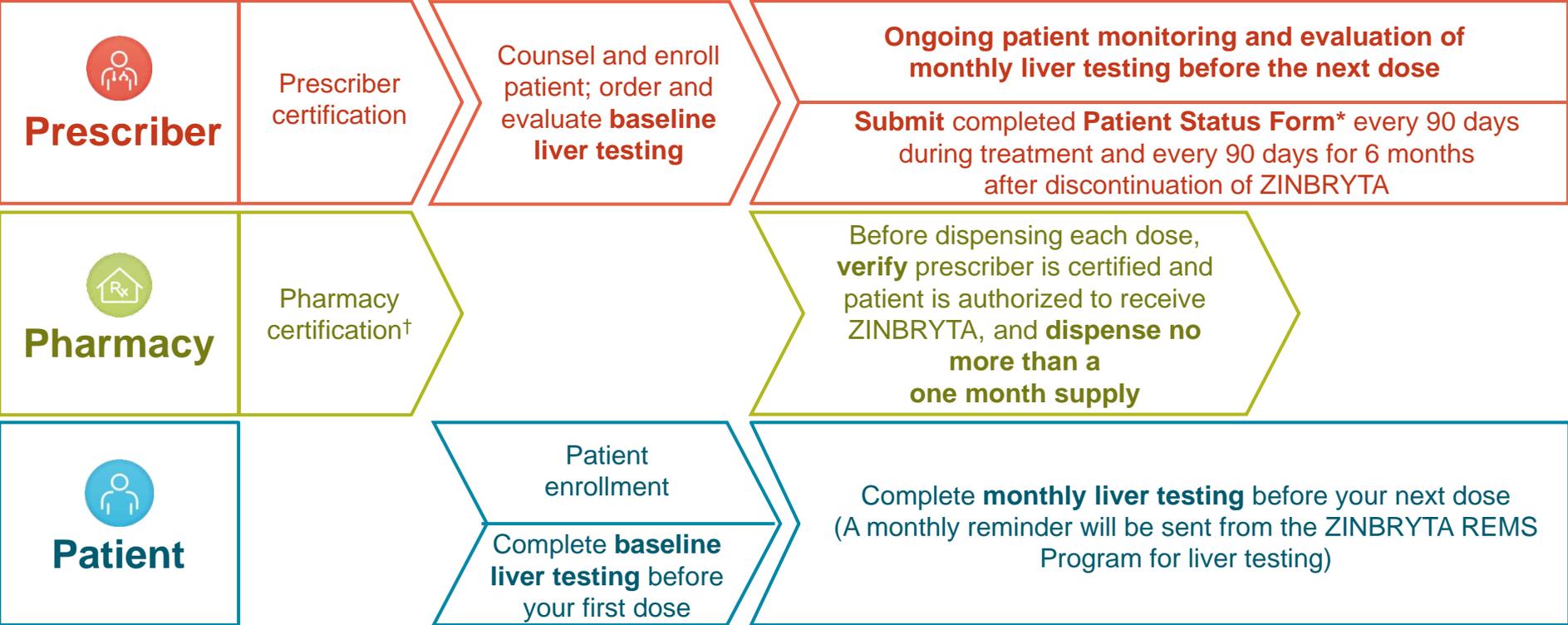
## What Is the ZINBRYTA REMS Program?

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- 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.



# Requirements and Roles of Prescribers, Pharmacies, and Patients



# What Are the Requirements of the ZINBRYTA REMS Program?

## Prescribers



### 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** 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:

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



### 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

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



## How Do I Communicate With the ZINBRYTA REMS Program?

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### Online



ZINBRYTA Program Portal  
[www.zinbrytarems.com](http://www.zinbrytarems.com)

### Phone



1-800-456-2255  
Monday-Friday

### Paper



Fax: 1-855-474-3067



## How Does a Prescriber Become Certified in the Program?



### Before prescribing ZINBRYTA

- Review** the following educational materials on ZINBRYTA to understand the risks of severe and life-threatening hepatic injury including autoimmune hepatitis, and serious immune-mediated disorders, and the REMS Program:
  - ZINBRYTA Prescribing Information
  - ZINBRYTA REMS Program Overview
  - ZINBRYTA REMS Program Prescriber Training
- Complete** and **submit** the ZINBRYTA REMS Program Prescriber Knowledge Assessment and the ZINBRYTA REMS Program Prescriber Enrollment Form, using the submission details at the end of this presentation
- Once completed, the ZINBRYTA REMS Program will notify you to finish certification. Within 2 business days upon receipt of your form, you will receive correspondence from the ZINBRYTA REMS Program. Correspondence will include:
  - How to retake the **ZINBRYTA REMS Program Prescriber Knowledge Assessment**, if necessary **OR**
  - A confirmation of your enrollment and certification in the ZINBRYTA REMS Program



# How Does a Prescriber Enroll Appropriate Patients in the Program?



## Before starting each patient on ZINBRYTA

- 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 below
  - **ZINBRYTA REMS Program Patient Guide**
  - **ZINBRYTA REMS Program Patient Wallet Card**
- Order and evaluate** the baseline liver testing before each patient's first dose of ZINBRYTA
- Submit** a completed ZINBRYTA REMS Program Patient Enrollment Form and prescription for each patient, store a copy in the patient's records. Your patient can expect to be contacted by the ZINBRYTA REMS Program



# What Are the Monitoring Requirements for Prescribers After Starting a Patient on ZINBRYTA?

Become Certified  
(One-time)

Enroll Your  
Patients

Monitor Your  
Patients

## Once your patient is on ZINBRYTA

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
2. **Submit** a completed ZINBRYTA REMS Program Patient Status Form\* for each patient **every 90 days** during treatment and **every 90 days for 6 months after discontinuation** of ZINBRYTA using the submission details at the end of this presentation
3. **Report** any adverse events suggestive of hepatic injury including autoimmune hepatitis, and other immune-mediated disorders to the ZINBRYTA REMS Program. You will be contacted for more information about these events
4. **Inform** the ZINBRYTA REMS Program if a patient is no longer under your care or has discontinued ZINBRYTA

\* 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.



# Overview of ZINBRYTA REMS Program Forms



# Prescribers Must Enroll Each Patient in the ZINBRYTA REMS Program

**ZINBRYTA REMS Program Patient Enrollment Form** **For Patients**

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. Your certified healthcare provider will help you complete this form and provide you with a copy. Fields marked with \* are required.

Please submit this completed form to the ZINBRYTA REMS Program via online, using the ZINBRYTA Program Portal, fax, or mail:  
www.zinbrytarems.com 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, please visit www.zinbrytarems.com or call: 1-800-456-2255.

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

**PATIENT INFORMATION (PLEASE PRINT)**

First Name\* Last Name\* Date of Birth\* Gender\*  Male  Female

Address\* City\* State\* ZIP\*

Email Primary Phone\* Secondary Phone

Preferred method(s) of contact:  Primary Phone  Email

In addition, I give permission and allow for the sharing of my health information to the designated individual named below. Biogen may contact the individual designated below to discuss my enrollment in the ZINBRYTA REMS Program.

Designated Individual Relationship

Email Address Phone Number

**PRESCRIBER INFORMATION (PLEASE PRINT)**

First Name\* Last Name\* Phone Number\* Prescriber NPI Number\*

**PATIENT AGREEMENT**

**By signing this form, I understand and acknowledge that:**

- 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 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.

**PATIENT ACKNOWLEDGMENT**

Patient/Patient Representative Signature Print Name Relationship to Patient Date

**PRESCRIBER ACKNOWLEDGMENT**

I have reviewed and discussed the risks of ZINBRYTA and the requirements of the ZINBRYTA REMS Program with this patient, and baseline liver testing will be completed prior to this patient's first dose of ZINBRYTA.

Prescriber Signature Date

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- Form includes:
  - Patient information and acknowledgment of REMS requirements.
  - Prescriber information, acknowledgment that this patient was counseled on the risks associated with ZINBRYTA, and that baseline testing will be completed prior to patient's first dose of ZINBRYTA.

- Missing information will prompt a follow-up from the ZINBRYTA REMS Program.
- Prescriber will be notified upon successful enrollment of each patient.



# ZINBRYTA REMS Program Patient Status Form: To Be Completed by Prescriber Every 90 Days While on Therapy and Every 90 Days for 6 Months Post Discontinuation

- Prescribers will receive an individualized ZINBRYTA REMS Program Patient Status Form for completion every 90 days during treatment and every 90 days for 6 months post discontinuation of ZINBRYTA.
- 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.

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

Unknown

Prescriber Name Prescriber Phone Number

**PATIENT STATUS**

1. This patient has completed required liver testing during the last 90 days:
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
    - May include elevated liver enzymes and/or total bilirubin:
      - ALT or AST >5x ULN **OR**
      - Total bilirubin >2x ULN **OR**
      - ALT or AST ≥3x ULN but <5x ULN and total bilirubin >1.5x ULN but <2x ULN
    - Or a suspected or confirmed diagnosis (e.g. autoimmune hepatitis)
  - b. Immune-mediated disorders
    - May include skin reactions, lymphadenopathy, autoimmune hemolytic anemia, immune-mediated 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:  
*If no, ZINBRYTA REMS will begin the disenrollment 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.*

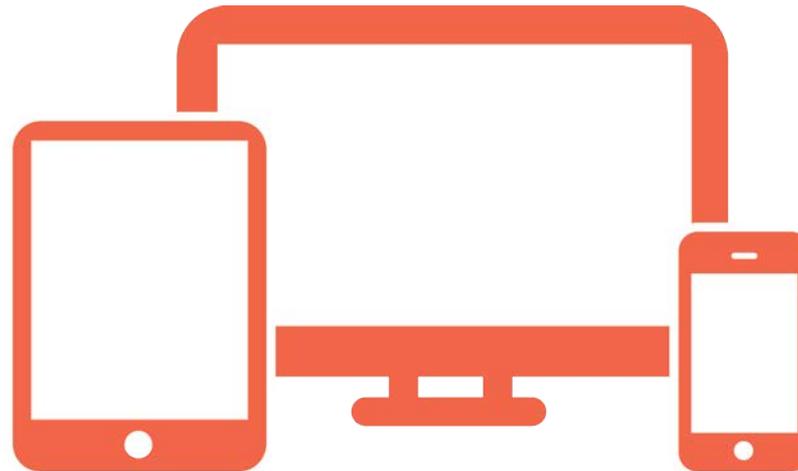
- Prescribers will be contacted to obtain missing information, based on responses provided, or if the form is not received.
- Please note that if the prescriber does not submit the form, it may result in a delay of the patient receiving ZINBRYTA.



## ZINBRYTA Program Portal Overview

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- 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.



If you have any questions regarding the ZINBRYTA REMS Program, please visit [www.zinbrytarems.com](http://www.zinbrytarems.com) or call: 1-800-456-2255.

Online: [www.zinbrytarems.com](http://www.zinbrytarems.com)

Fax: 1-855-474-3067

Mail: 5000 Davis Drive, PO Box 13919, Research Triangle Park, NC 27709



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 **Zinbryta<sup>®</sup>**  
(daclizumab)  
150mg Subcutaneous Injection