

Medication Guide
ZINBRYTA® (zin-bry-tuh)
(daclizumab)

injection, for subcutaneous use

What is the most important information I should know about ZINBRYTA?

ZINBRYTA can cause serious side effects, including:

- **Liver problems.** ZINBRYTA may cause serious liver problems (including autoimmune-related liver problems) that may lead to death. Your healthcare provider should do blood tests to check your liver before you start using ZINBRYTA, every month while you are using ZINBRYTA, and monthly for 6 months after you stop using ZINBRYTA. Your healthcare provider should check your test results before your next dose.

Call your healthcare provider right away if you have any of the following symptoms of liver problems:

- 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 system attacks healthy cells in their body) and other immune system problems.

Call your healthcare provider right away if you have any of the following symptoms:

- 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, 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

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.

- Before you begin using ZINBRYTA, you must enroll in the ZINBRYTA REMS Program. Talk to your healthcare provider about how to enroll in the ZINBRYTA REMS Program.
- ZINBRYTA can only be given at a certified pharmacy that participates in the ZINBRYTA REMS Program. Your healthcare provider can give you information on how to find a certified pharmacy.
- Your healthcare provider or pharmacist will give you a ZINBRYTA Patient Wallet Card along with this Medication Guide. It has important information about ZINBRYTA and should be carried with you at all times. Show the ZINBRYTA Patient Wallet Card to all of your healthcare providers so that they know you are being treated with ZINBRYTA.

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. It is not known if ZINBRYTA is safe and effective for use in children under 18 years of age.

Do not use ZINBRYTA if you:

- have liver problems
- have or have had autoimmune-related liver problems including autoimmune hepatitis
- are allergic to daclizumab or any of the other ingredients in ZINBRYTA. See the end of this Medication Guide for a complete list of ingredients in ZINBRYTA.

Before using ZINBRYTA, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems
- have or have had skin problems including eczema or psoriasis
- have tuberculosis
- have an active infection
- are planning to receive a vaccine
- have or have had depression
- are pregnant or plan to become pregnant. It is not known if ZINBRYTA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZINBRYTA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use ZINBRYTA.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Using ZINBRYTA with other medicines can cause serious side effects.

How should I use ZINBRYTA?

- Use ZINBRYTA exactly as your healthcare provider tells you. A healthcare provider should show you how to inject ZINBRYTA before you use it for the first time.
- Inject ZINBRYTA 1 time every month. Try to keep to a particular day of the month to help remember your injection. For example, inject on the first day of each month.
- ZINBRYTA is for use under the skin (subcutaneous injection) of your thigh, stomach (abdomen), or back of the upper arm.
- If you miss a dose of ZINBRYTA, inject your dose of ZINBRYTA as soon as possible within 2 weeks of the missed dose. If it is more than 2 weeks after your missed dose, skip the missed dose. Inject your next dose on schedule. Do not inject more than 1 dose of ZINBRYTA at a time.
- Your healthcare provider should do blood tests before you start ZINBRYTA, every month during your treatment with ZINBRYTA, and monthly for 6 months after you have stopped using ZINBRYTA to check for side effects. Your healthcare provider should check your test results before your next dose.
- ZINBRYTA comes as a:
 - Single-Dose Prefilled Autoinjector (ZINBRYTA Pen)
 - Single-Dose Prefilled SyringeYour healthcare provider will decide which one is best for you. See the **Instructions for Use** that come with ZINBRYTA for detailed instructions on using ZINBRYTA the right way.

Always use a new, unopened, single-dose prefilled autoinjector or single-dose prefilled syringe for each injection. Throw away any unused medicine. **Do not** re-use any syringes, needles or pens.

What are the possible side effects of ZINBRYTA?

ZINBRYTA can cause serious side effects, including:

- See **"What is the most important information I should know about ZINBRYTA?"**
- **Allergic reactions or serious problems that may affect different parts of the body such as your liver, kidneys, heart or blood.** These can be very serious and can cause death. Call your healthcare provider right away if you have any of the following symptoms while using ZINBRYTA:
 - fever
 - rash
 - swelling of the face, tongue or throat
 - trouble breathing
- **Infections.** Some people who use ZINBRYTA may get an infection, such as an upper respiratory tract infection or a urinary tract infection. Some infections may be serious. Call your healthcare provider if you have symptoms of an infection. Talk to your healthcare provider before you get vaccinations while using ZINBRYTA.
- **Depression and suicide.** Some people who use ZINBRYTA may develop depression, depressed mood, or suicidal thoughts. Call your healthcare provider right away if you have ever been treated for depression or have any of the following symptoms while using ZINBRYTA:
 - feel sad or have crying spells
 - are sleeping a lot more or a lot less than usual
 - feel hopeless or helpless
 - are more irritable, angry or aggressive than usual
 - have trouble paying attention
 - feel tired or sleepy all the time
 - have thoughts about hurting yourself or ending your life

The most common side effects of ZINBRYTA include:

- upper respiratory tract infection
- flu
- pain or swelling in your nose, throat, or mouth
- bronchitis
- abnormal liver function tests
- dry, itchy, scaly, or inflamed skin (eczema)
- rash
- depression and depressed mood
- swollen lymph glands

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of ZINBRYTA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZINBRYTA?

- Store ZINBRYTA in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton.
- **Do not** freeze ZINBRYTA. **Do not** use ZINBRYTA that has been frozen.
- **Do not** store ZINBRYTA at temperatures above 86°F (30°C).
- Keep ZINBRYTA away from light.
- If you cannot refrigerate ZINBRYTA, you can store ZINBRYTA at room temperature for up to 30 days.
- If ZINBRYTA has reached room temperature, **do not** put it back in the refrigerator. Throw away ZINBRYTA that has been outside of the refrigerator for more than 30 days.

Keep ZINBRYTA and all medicines out of the reach of children.

General Information about the safe and effective use of ZINBRYTA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZINBRYTA for a condition for which it was not prescribed. Do not give ZINBRYTA to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about ZINBRYTA that is written for health professionals. For more information, go to zinbryta.com or call 1-800-456-2255.

What are the ingredients in ZINBRYTA?

Active ingredient: daclizumab

Inactive ingredients:

- **Single-Dose Prefilled Autoinjector:** sodium succinate, anhydrous; succinic acid; sodium chloride; polysorbate 80 and water for injection.
- **Single-Dose Prefilled Syringe:** sodium succinate, anhydrous; succinic acid; sodium chloride; polysorbate 80 and water for injection.

Manufactured by: Biogen Inc., Cambridge, MA 02142; Distributed by: AbbVie Inc., North Chicago, IL 60064

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This Medication Guide has been approved by the U.S. Food and Drug Administration

Issued: 08/2017