

Daclizumab (Zinbryta)

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Patient Information

SPECIAL ALERT

- **Voluntary Worldwide Market Withdrawal 3/2/2018** due to 8 cases of encephalitis (brain inflammation) in Europe
- Contact your health care provider if you are currently being treated with Daclizumab (Zinbryta)
- More information: <http://media.biogen.com/press-release/autoimmune-diseases/biogen%C2%A0and-abbvie-announce%C2%A0voluntary%C2%A0worldwide-withdrawal-marketi>.

USED FOR

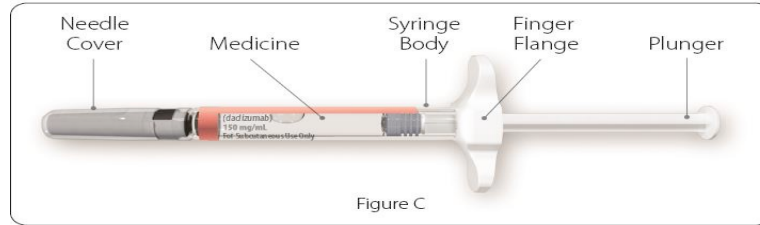
- Relapsing forms of multiple sclerosis (MS)
- Daclizumab will not cure MS. It may reduce flare-ups and slow disease progression.

HOW IT WORKS

- Daclizumab is an antibody that suppresses the immune system by targeting cells that regulate the immune system, which is thought to help reduce injury to the nervous system from MS.

HOW IT IS SUPPLIED

- Daclizumab comes in a single-dose prefilled syringe with 150mg dose




DOSE

- 1 mL (150 mg) injected under the skin once monthly (every 4 weeks)

HOW IT IS GIVEN

- Daclizumab should be out of the refrigerator for at least 30 minutes before using
- Using the prefilled syringe, Daclizumab is injected into the fatty area just under the skin in the areas shown below
- You may rotate injection sites to avoid skin reactions.



<p>STORAGE AND HANDLING</p>	<ul style="list-style-type: none"> When not used, Daclizumab should be stored in the refrigerator. If refrigeration is not possible, Daclizumab may be stored protected from light up to 30°C (86°F) for up to 30 days. Safely dispose of syringes in a sharps container. 	
<p>DRUG INTERACTIONS</p>	<ul style="list-style-type: none"> Do not take any medications that can be harmful to your liver such as, over the counter medications, herbal products, or dietary supplements. If you are not sure, please check with your MS doctor or pharmacist. Avoid excessive amounts of alcohol to prevent harm to your liver 	
<p>COMMON SIDE EFFECTS</p>	<ul style="list-style-type: none"> Abnormal liver function tests Dry, itchy, scaly, or inflamed skin (eczema) not related to the injection site Rash Upper respiratory tract infection 	<ul style="list-style-type: none"> Flu Pain or swelling in your nose, throat, or mouth Bronchitis Depression and depressed mood Swollen lymph glands
<p>RARE, BUT SERIOUS SIDE EFFECTS</p>	<ul style="list-style-type: none"> Daclizumab may cause serious liver problems (including auto-immune related liver problems) that may lead to death Call your healthcare provider right away if you have any symptoms of liver problems: nausea or vomiting, stomach pain, unusual tiredness, not wanting to eat, yellowing of the skin or whites of your eyes, and dark urine Other serious symptoms: <ul style="list-style-type: none"> Mild to severe skin rash or irritation Tender, painful, or swollen lymph nodes Symptoms of intestinal problems such as fever, blood in stool, or diarrhea that does not go away Depression or irritability 	
<p>MONITORING</p>	<ul style="list-style-type: none"> BEFORE starting Daclizumab, you will need a complete blood count, lymphocyte subsets, liver function tests, testing for viral hepatitis, and tuberculosis. Prior to each monthly dose thereafter, you will need a monthly liver function test. If you stop using Daclizumab, you will still need monthly liver function tests for 6 months. <i>All monthly liver function tests after the first dose are free of charge via a program with LabCorp and EMSI home phlebotomy services</i> 	
<p>AFTER YOUR FIRST DOSE</p>	<ul style="list-style-type: none"> Mark on your personal calendar the date of your first injection, schedule your blood work for liver function tests in 2 to 3 weeks, and schedule your next dose approximately 4 weeks after your first dose. Call your pharmacy to let them know when your next dose is due so that they deliver Daclizumab on time. If you miss a dose, inject your dose as possible within 2 weeks of the missed 	

dose. Do not inject 2 doses at the same time.

MORE INFORMATION

- Websites: www.zinbryta.com, www.nationalmssociety.org
- Clinical Trials:
 1. Kappos L, et al. N Engl J Med 2015;373:1418-28.
 2. Gold R, et al. Lancet 2013; 381:2167-75.