May 2018

ZINBRYTA REMS Program Letter for Healthcare Providers

Subject: Risk of severe and fatal liver injury, including autoimmune hepatitis and liver failure, and other immune-mediated disorders with ZINBRYTA (daclizumab)

Dear Healthcare Provider:

The purpose of this letter is to inform you about serious risks associated with ZINBRYTA (daclizumab) injection and the need for monitoring for these risks. 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.

The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of ZINBRYTA outweigh the serious risks. 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.

Serious Risks of ZINBRYTA

Hepatic Injury Including Autoimmune Hepatitis

ZINBRYTA can cause severe liver injury, including autoimmune hepatitis and liver failure. Fatal cases have occurred. 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.

ZINBRYTA is contraindicated in patients with pre-existing hepatic disease or hepatic impairment.

Other Immune-Mediated Disorders

In addition to autoimmune hepatitis, a variety of immune-mediated disorders including skin reactions, lymphadenopathy, and immune-mediated colitis, and other serious conditions can occur in patients treated with ZINBRYTA. Overall, serious immune-mediated disorders were observed in 5% of patients treated with ZINBRYTA.

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.

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.

ZINBRYTA Healthcare Provider Training

It is important that healthcare providers understand the serious risks associated with ZINBRYTA. As part of the REMS, healthcare providers must be trained and specially certified to prescribe ZINBRYTA.

ZINBRYTA REMS Program training materials for healthcare providers may be obtained at www.zinbrytarems.com or by calling 1-800-456-2255.

Reporting Adverse Events

Healthcare providers and patients are encouraged to report adverse events in patients taking ZINBRYTA to Biogen at 1-800-456-2255. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Healthcare providers should report any adverse events suggestive of hepatic injury and immune-mediated disorders with the use of ZINBRYTA to Biogen at 1-800-456-2255.

All REMS information/materials may be accessed at www.zinbrytarems.com or by calling 1-800-456-2255.

Please see the enclosed Prescribing Information for ZINBRYTA.

Sincerely,

Alfred Sandrock
EVP, Chief Medical Officer
Biogen

Biogen abbvie