Generic Name:
Daclizumab
Trade Name:
Zinbryta
Company:
Biogen, AbbVie
Notes:

Biogen and AbbVie are voluntarily withdrawing daclizumab, a multiple sclerosis (MS) drug, from the global market, noting concern about the drug?s evolving benefit/risk profile.

FDA announced it is working closely with the manufacturers to help ensure a well-organized withdrawal from the market in the United States and to ensure that health professionals have the information they need to carefully transition their patients using daclizumab to another treatment. No new patients will start taking daclizumab or participate in clinical studies.

The company has begun notifying health professionals and patients, and the drug will be available for patients as needed until April 30, 2018.

Patients using daclizumab should not stop their medication without talking with their doctor and should contact their doctor immediately if they have any new and unexplained symptoms. Any questions or concerns about the withdrawal can be directed to the manufacturers? service center at 800-456-2255 or the manufacturer?s website at www.zinbryta.com. FDA stated that it understands that this may be a difficult situation for some patients and will continue to work closely with the manufacturers throughout the withdrawal process.

The complex safety profile of daclizumab has been recognized since the time of FDA approval. The drug?s safety profile led to an indication of use generally limited to patients who have had an inadequate response to two or more MS drugs, to a boxed warning about the risk of liver injury and of other immune-mediated disorders, and to a Risk Evaluation and Mitigation Strategy making the drug available only through a restricted distribution program.

FDA has continuously monitored adverse events associated with use of daclizumab and has updated product labeling as new information became available.

Recently, the European Medicines Agency announced a recall of daclizumab following 12 reports of serious inflammatory brain disorders worldwide. FDA is aware of these reports and is conducting a review of similar events. As the manufacturers move forward the withdrawal plan, any additional important information will be made available to the public.

FDA asks health professionals and consumers to report any adverse reactions or quality problems to FDA?s MedWatch program at www.fda.gov/medwatch/report.htm.

Medication Monitor Categories:
Product Withdrawals