Liver tests
(serum aminotransferase, alkaline phosphatase, and total bilirubin)

Repeat as cli

Learn more

One pill, twice daily[1]

Start
7 days with 120 mg twice daily

AM  **120 mg**

PM  **120 mg**

Conti
with 240 mg

AM 

PM 

- One pill, twice a day
- Can be taken with or without food
- Should be swallowed whole and intact, not crushed or chewed, and the capsule contents should n
- Temporary dose reductions to 120 mg twice a day may be considered for individuals who do not t Within 4 weeks, the recommended dose of 240 mg twice a day should be resumed
- Discontinuation of TECFIDERA should be considered for patients unable to tolerate return to the m

IMPORTANT SAFETY INFORMATION AND INDICATION

with the content.

Welcome Kit

Delivered to patients once you've prescribed TECFIDERA. Each kit includes a welcome bro
patients start and stay on TECFIDERA and get the most out of treatment.

TecTrack™ App

The TecTrack™ app helps patients remember to take their medication and is available for d
or Google Play.

Available on the App Store

Get it on Google play

ABOVE MS™
Brought to you by Biogen

The Above MS™ program from Biogen supports you and your patients with tips, tools, and more:

- Personalized support from people who are here to help
- One-on-one RMS support by phone
- Nurse Educators are available by phone 24/7
- A variety of financial and insurance support services for eligible patients

Learn more about Above MS™

Fill out a Start Form to help your patients get the support they need.

Download Start Form

QuickStart can help eligible patients with free 7-day samples of 120 mg TEC

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signs and symptoms of anaphylaxis and angioedema (which have included difficulty breathing, urticaria, and should discontinue TECFIDERA and seek immediate medical care.

Progressive multifocal leukoencephalopathy (PML) has occurred in patients with MS treated with TECFIDERA infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocom death or severe disability. A fatal case of PML occurred in a patient who received TECFIDERA in a clinical tria postmarketing setting in the presence of lymphopenia (<0.8x10^9/L) persisting for more than 6 months. While cases is uncertain, the majority of cases occurred in patients with lymphocyte counts <0.5x10^9/L. The sympt diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsine and changes in thinking, memory, and orientation leading to confusion and personality changes. At the first s PML, withhold TECFIDERA and perform an appropriate diagnostic evaluation. MRI findings may be apparent

TECFIDERA may decrease lymphocyte counts; in clinical trials there was a mean decrease of ~30% in lympho which then remained stable. Four weeks after stopping TECFIDERA, mean lymphocyte counts increased but TECFIDERA patients and <1% of placebo patients had lymphocyte counts <0.5x10^9/L. TECFIDERA has not be existing low lymphocyte counts.

There was no increased incidence of serious infections observed in patients with lymphocyte counts <0.8x10 trials, although one patient in an extension study developed PML in the setting of prolonged lymphopenia (ly <0.5x10^9/L for 3.5 years). In controlled and uncontrolled clinical trials, 2% of patients experienced lymphocyte months. In these patients, the majority of lymphocyte counts remained <0.5x10^9/L with continued therapy. A lymphocyte count should be obtained before initiating treatment, 6 months after starting, every 6 to 12 mont indicated. Consider treatment interruption if lymphocyte counts <0.5x10^9/L persist for more than six months until lymphopenia is resolved. Consider withholding treatment in patients with serious infections until resolve to restart TECFIDERA should be based on clinical circumstances.

Clinically significant cases of liver injury have been reported in patients treated with TECFIDERA in the postm ranged from a few days to several months after initiation of treatment. Signs and symptoms of liver injury, in aminotransferases to greater than 5-fold the upper limit of normal and elevation of total bilirubin to greater th have been observed. These abnormalities resolved upon treatment discontinuation. Some cases required ho cases resulted in liver failure, liver transplant, or death. However, the combination of new serum aminotransfe levels of bilirubin caused by drug-induced hepatocellular injury is an important predictor of serious liver injury failure, liver transplant, or death in some patients.

Elevations of hepatic transaminases (most no greater than 3 times the upper limit of normal) were observed

Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels before initiating TECFIDERA a indicated. Discontinue TECFIDERA if clinically significant liver injury induced by TECFIDERA is suspected.

TECFIDERA may cause flushing (e.g. warmth, redness, itching, and/or burning sensation). 40% of patients tak which was mostly mild to moderate in severity. Three percent of patients discontinued TECFIDERA for flushin events that led to hospitalization. Taking TECFIDERA with food may reduce flushing. Alternatively, administra prior to dosing may reduce the incidence or severity of flushing.

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