Once-daily AUBAGIO® (teriflunomide) 14 mg tablets

genzyme
A SANOFI COMPANY

Fact Sheet

AUBAGIO® (teriflunomide) is a once-daily, oral treatment indicated by the U.S. Food and Drug Administration (FDA) in September 2012 for the treatment of patients with relapsing forms of multiple sclerosis (MS).

DOSING

AUBAGIO is available in a **14 mg oral tablet** to be taken **once daily**. It can be administered with or without food.

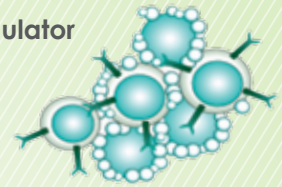
A 7 mg oral tablet is also available.

EFFICACY

AUBAGIO 14 mg has shown significant efficacy versus placebo across key measures of MS disease activity, including **reducing relapses, slowing the progression of physical disability**, and **reducing the number of brain lesions** as detected by MRI.

MECHANISM OF ACTION

AUBAGIO works differently than other MS therapies. AUBAGIO is an **immunomodulator** with anti-inflammatory properties. Although the exact mechanism of action for AUBAGIO is not fully understood, it may involve a reduction in the number of activated **lymphocytes, also known as T- and B- cells,** in the central nervous system (CNS) that may cause MS inflammation.



CLINICAL TRIAL PROGRAM

AUBAGIO is supported by a robust clinical program that is estimated to include more than **5,000 trial participants in 36 countries** and is amongst the largest of any MS therapy. Some patients in extension trials have been treated for up to 10 years.

The FDA approval of AUBAGIO is based on data from the **TEMSO (TEriflunomide Multiple Sclerosis Oral)** trial that show AUBAGIO 14 mg significantly reduced the annualized relapse rate and the time to disability progression at two years versus placebo in patients with relapsing forms of multiple sclerosis. AUBAGIO 7 mg significantly reduced the annualized relapse rate in the trial.

The AUBAGIO clinical development program in MS also included the **TOWER (Teriflunomide Oral in people With relapsing remitting multiplE scleRosis)** study. TOWER assessed the efficacy and safety of once-daily, oral AUBAGIO in patients with relapsing forms of MS. In the study, patients receiving teriflunomide 14 mg had a statistically significant reduction in annualized relapse rate and risk of disability progression. In addition, a significant reduction in annualized relapse rate was observed in patients treated with teriflunomide 7 mg compared to placebo. Adverse events observed in the trial were consistent with previous clinical trials with teriflunomide in MS.

AUBAGIO SAFETY PROFILE

The AUBAGIO label includes a boxed warning citing the risk of hepatotoxicity and, teratogenicity (based on animal data).

In MS clinical studies with AUBAGIO, the incidence and nature of serious adverse events were similar among AUBAGIO and placebo-treated patients. The most common adverse events associated with AUBAGIO in MS patients included increased ALT levels, alopecia, diarrhea, influenza, nausea and paresthesia.

Teriflunomide is the principal active metabolite of leflunomide, which is indicated in the U.S. for the treatment of rheumatoid arthritis. Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide.

AUBAGIO is contraindicated in patients with severe hepatic impairment, in pregnant women, in women of childbearing potential who are not using reliable contraception, and in patients currently taking leflunomide.