

A New Oral medication for MS is approved by FDA!!

A new oral medication, Teriflunomide (Aubagio®), was approved by FDA on 9/12/2012 for the treatment of relapsing forms of multiple sclerosis. **Aubagio® is the ninth disease-modifying therapy available for the treatment of MS, and the second after Fingolimod (Gilenya) that is taken by mouth.** Aubagio® is a pill given once per day, and is available in two strengths, 7 mg and 14 mg.

How does Teriflunomide (Aubagio®) work?

MS is believed to be an autoimmune process where cells from the immune system, T lymphocytes and B lymphocytes, produce inflammation and damage of the white matter and nerve cells in different parts of the brain and spinal cord.. Aubagio® works by interfering in the proliferation of those cells from the immune system that target the brain. It does not interfere with immune cells that are not in an active stage of damage against the brain.

How was Teriflunomide (Aubagio®) tested in MS?

Two large clinical trials were conducted to test the effectiveness and safety of Aubagio®. The action of Aubagio® was shown in clinical trials to reduce the annual rate of relapses and also the development of new areas of inflammation and damage within the central nervous system. Importantly, there was also a statistically significant effect on the delay of disability over the two years of each clinical trial.

The first trial, called the “TEMPO” trial compared two doses of Aubagio® (7 mg/day and 14 mg/day) to a group of patients receiving placebo. 1088 people with relapsing MS were randomly assigned to one of the three groups. 796 participants completed the study. The number of relapses was reduced by 31.5% and the high dose (14mg/day) group had less progression of disability. There were fewer new MRI lesions in the treated groups.

A second large Phase III, called the “TOWER” trial also demonstrated efficacy of Aubagio®. In this trial, there were 1169 participants. This was a 48 week trial with three groups. Participants were randomly assigned to the 7 mg/day, 14 mg/day or placebo groups. Results from this trial demonstrated a reduction in relapses of 36.3% in the 14 mg/day group. In addition, the time to disability progression was reduced by 31.5%.

How does Teriflunomide (Aubagio®) compare with other medications for MS?

There has been only one study comparing Aubagio® with one available medication for MS, Rebif®. A large clinical trial of 324 participants compared the two doses of Aubagio® to Rebif® 44 mcg three times per week subcutaneously. The primary endpoint of the study was “risk of failure” meaning the first occurrence of a relapse. Relapse rates were similar for the Aubagio® and Rebif® treated groups. However, Aubagio® hasn’t been compared in clinical trial with other immunomodulatory medications (e.g. Copaxone® or Avonex®).

What are the side effects of Teriflunomide (Aubagio®)?

As other medications used in MS, Aubagio® may cause side effects. These include GI upset (nausea, diarrhea), hair thinning, back discomfort, elevated liver enzymes, flu, low white blood cell count, increased risk of infection and increased blood pressure. This drug has *Pregnancy category “X”* which means that women of child bearing potential must use reliable contraception while on this drug and for up to 6 months after discontinuation of the drug. The drug can be cleared from the system within 11 days by the use of cholestyramine or activated charcoal.

Is there any need for monitoring, such as blood tests, while on treatment with Teriflunomide (Aubagio®)?

There is need for initial monitoring of liver function tests in patients receiving Aubagio®. Blood tests to monitor liver enzymes are needed before starting Aubagio® and *every month for the first 6 months* and periodically thereafter.

Patients must follow-up regularly with their neurology provider to monitor for infections, elevations in blood pressure, and for regular blood tests.

Who can receive Teriflunomide (Aubagio®)? Or Which patients can switch from the current injectables to Teriflunomide (Aubagio®)?

Teriflunomide (Aubagio®) was tested in patients with relapsing multiple sclerosis. In this type of MS, new symptoms that develop and last at least 24 hours and are in the absence of a fever or other metabolic cause are called relapses or exacerbations. Symptoms will usually persist for a few weeks or even months. Recovery may be 100% or sometimes less than 100%. There is usually a period of clinical stability (remission) in between episodes (relapses).

Teriflunomide (Aubagio®) has not been tested in patients with secondary-progressive or primary-progressive MS in any large clinical trials.

Teriflunomide (Aubagio®) is indicated for relapsing MS. If you are interested in knowing if Teriflunomide (Aubagio®) is right for you, please discuss this with your MS provider.

For more information about teriflunomide (Aubagio®), please go to the Genzyme website: www.MSONEtoOne.com or call 1-855-676-6326.