

AubagioTM
(teriflunomide)

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MS Treatments

MSology Essentials Series

Aubagio™

(teriflunomide)

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Why treat MS?

Multiple sclerosis (MS) is believed to be caused by an abnormal immune response, which results in inflammation and tissue damage in the brain and spinal cord (together called the central nervous system, or CNS). This inflammation is the cause of MS symptoms, such as nerve tingling, muscle weakness, vision problems, balance difficulties and pain. New or worsening MS symptoms that last for more than a day or two are called relapses, and these generally indicate an inflammatory flare-up in the CNS. Relapse symptoms can persist for several weeks or months. Some relapses will resolve completely and some will not. As you experience more and more relapses, the body is unable to repair the damage to the brain and spinal cord, which typically leads to physical and mental impairments.

That is why it is so important to treat MS – to reduce inflammation and tissue damage, and reduce or delay disability. The medications prescribed are called disease-modifying therapies because they target the underlying MS disease process. They do not heal any tissue damage that has already occurred, but they may prevent further damage that will contribute to disability in the years ahead.

MS medications do not treat specific symptoms, so you will not feel an improvement in the symptoms you are having. The main effects of therapy are to lessen the frequency and severity of relapses, and reduce the amount of inflammation in the brain and spinal cord. So treatment can be seen as an investment in your future – lessening the often silent damage that is occurring now to prevent disabilities later on.



How does Aubagio work?

Aubagio (teriflunomide) is an oral medication (pill) used to treat relapsing-remitting multiple sclerosis.

In MS, specialized cells of the immune system become activated, enter the CNS and cause inflammation and tissue damage. Aubagio blocks the production of these overactive immune cells so there are fewer cells available to attack the body's own tissues. As a result, Aubagio modulates the abnormal immune response seen in MS, and has anti-inflammatory effects in the CNS.

Clinical trials of Aubagio have shown that it reduces the rate of relapses, lowers the risk of worsening disability, and suppresses inflammatory lesions in the brain in people with MS.



Aubagio is a once-daily pill – but you must remember to take it every day to get the full benefit of treatment. The medication will be less effective in controlling your MS if you skip doses from time to time.



How do I take Aubagio?

Dosing

Aubagio must be taken once per day.

1x
a day

Aubagio is a pill (14 mg) and is taken by mouth.



Aubagio may be taken with or without food.



Considerations

Try to get into a routine of taking it at the same time each day, such as with breakfast or with your evening meal.



If you forget to take a dose, do not double up the dose. Take your pill as soon as you remember (e.g. at lunch if you forgot at breakfast) or when you would normally take the next dose (e.g. at breakfast).





How do I know my treatment is working?

During your course of treatment, your doctor will monitor your response to treatment with a variety of tests and procedures. These typically include neurological examinations to evaluate your nerve and muscle function, and magnetic resonance imaging (MRI) to assess the extent of inflammatory activity in your brain and spinal cord. Other tests and procedures may also be needed during your course of treatment.

What if I have a relapse?

A *relapse* is a new MS symptom you haven't had before, or a worsening of symptoms you've previously experienced. The symptom persists for at least 24 hours. If you become overheated – from exercise, a hot bath, a fever or infection – your MS can worsen for a shorter period of time, but these symptoms are not a true relapse.

You may have a relapse in the first few months after starting treatment, especially if your MS was very active before. This doesn't mean your medication is not working. You will only experience the full benefit of your MS medication after you've been taking it continuously for a few months.

It's important to inform your neurologist or MS nurse if you experience a relapse or any new or worsening symptoms that last more than 24 hours.



What are the possible side effects of Aubagio?

Hair thinning

About 1 in 10 people may notice that there are extra hairs in their brush or comb. If this happens, it is most likely to occur after taking Aubagio for a few months. Hair thinning is not baldness, and the effect is generally temporary. It usually takes about six months for the natural hair cycle to replace the lost hairs.

Effects on the liver

Regular blood tests are needed while taking Aubagio. Tests are more frequent in the first six months after starting treatment, and less frequent thereafter. These tests are to ensure that your liver is functioning normally. Report any symptoms of liver problems to your doctor immediately. These symptoms may include unexplained nausea/vomiting, abdominal pain, dark urine, yellowing of the skin (jaundice), loss of appetite and unusual tiredness. Try to avoid consuming alcohol while taking Aubagio.

All medications have the potential to cause a variety of side effects. If you experience any new, unusual or worrisome symptoms while taking your medication, report them promptly to your doctor or MS nurse. Your MS nurse can often provide helpful advice to minimize any unwanted medication-related effects you may experience.

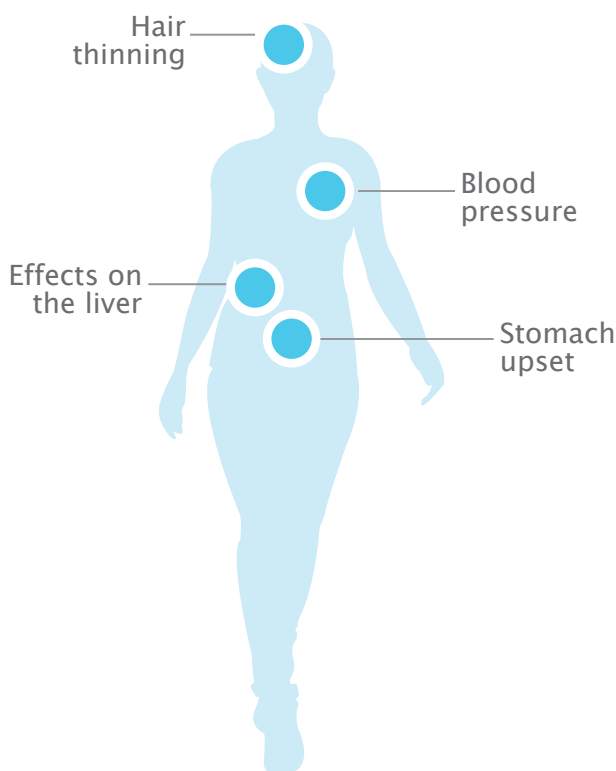


Stomach upset

Some people may experience stomach upset such as nausea, abdominal pain and diarrhea. It's best to take Aubagio with food if the medication upsets your stomach. These side effects usually subside after 1-2 months on treatment.

Blood pressure

Some people may experience a slight elevation in their blood pressure.





Tests and procedures

During your course of treatment, your doctor will order a number of tests to ensure that your medication is not causing any unwanted effects. Some of the suggested tests are listed in the table. However, your neurologist and MS nurse will schedule which tests you will need and how often they should be done.

The tests you may need during treatment with Aubagio*

Test/ procedure	Reason	How often
Blood test	To monitor liver function	<ul style="list-style-type: none">• Before starting Aubagio• Once a month or so for the first six months• Periodically according to your physician
	The blood test will also be used to determine your complete blood cell count (CBC)	<ul style="list-style-type: none">• Before starting Aubagio• If you develop signs of an infection
Blood pressure monitoring	To assess blood pressure (hypertension)	<ul style="list-style-type: none">• Before starting Aubagio• Periodically according to your physician
Pregnancy test (if applicable)	To ensure you are not pregnant	<ul style="list-style-type: none">• Before starting Aubagio• If pregnancy is suspected during treatment
Skin or blood test	To ensure that you don't have tuberculosis (TB)	<ul style="list-style-type: none">• Before starting Aubagio

*Your neurologist or MS nurse will tell you more about the testing you'll need during treatment. Please ensure that you have all of the necessary tests at the recommended times.



Pregnancy

It's generally advisable to avoid taking medications during pregnancy because they may cause harm to the developing fetus. The best approach is to talk to your doctor or MS nurse before becoming pregnant so you can work out a schedule for stopping and re-starting your medication.



Aubagio should not be taken during pregnancy or breastfeeding



Women and men should use a reliable method of contraception while taking Aubagio. Talk to your doctor or MS nurse if you are planning a pregnancy in the next few months.



Women and men must use a reliable method of contraception during treatment with Aubagio.

Talk to your neurologist or MS nurse if you are planning to become pregnant soon. Simply stopping Aubagio isn't sufficient because the drug stays in the body for a long time. You will need to actively eliminate the drug from your body. This will mean taking cholestyramine or activated charcoal for 11 days. A blood test will then confirm that the drug has been removed from the body. Cholestyramine and activated charcoal affect how your body absorbs medications, including oral contraceptives, so another method of birth control should be used during the period when you are taking cholestyramine or activated charcoal.

Women who become pregnant during treatment with Aubagio should stop taking the drug and contact their doctor immediately so the drug can be actively removed from the body.

Aubagio should not be taken during pregnancy or breastfeeding. Aubagio may be re-started once the baby has been weaned.



Other medications

All medications have the potential to interact with other drugs you are taking. This includes other prescription medications, as well as non-prescription drugs and alternative/complementary therapies. Some of these medications can also worsen MS symptoms.

Talk to a healthcare professional before taking any new medication. Your doctor, MS nurse or pharmacist can advise you about interactions that may occur with Aubagio and the other medications you are taking.

Other medical conditions

Always ensure that your doctor is aware of any other medical conditions you may have. This includes high blood pressure, liver problems, diabetes, infections, or other illnesses.

Resources in your community

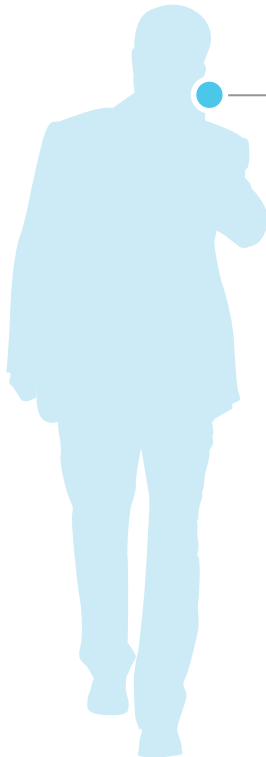
Your neurologist or MS nurse will talk to you about the **MS One to One™ program**, which provides information and support for people taking Aubagio.

Your local pharmacist can also provide important advice on your medication, how to take it, and what other medications (including non-prescription and alternative/complementary therapies) to avoid.



Contacting your MS nurse

Contact your MS nurse if you have any questions or concerns about your medication. It is important to notify your doctor or MS nurse if you have any new, worrisome or unusual symptoms that may be related to your medication, or any worsening of your MS symptoms.




Notify your doctor or MS nurse if you have any new symptoms



Notes

The MS Essentials series provides the latest information on multiple sclerosis medications, research, and lifestyle issues such as health, nutrition and exercise. All of the booklets are developed by Lind Publishing, publishers of MSology, to help people affected by MS remain active and informed. MS Essentials is provided free of charge. The full series of publications is available for download on <http://www.MSology.com>.

The information reflects use of the medication in Canada; use may vary in other countries. MSology does not approve, endorse or recommend any specific product or therapy. Contact your healthcare providers before you start treatment, alter the dose, interrupt or discontinue your therapy. For full information about a specific medication, consult the prescribing information or package insert provided by the manufacturer for your country.





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For more multiple sclerosis information, visit www.MSology.com

