

PART III: CONSUMER INFORMATION**AUBAGIO®
Teriflunomide tablets**

This leaflet is part III of a three-part "Product Monograph" published when AUBAGIO was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AUBAGIO. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

AUBAGIO is used to treat adult patients with relapsing remitting multiple sclerosis (RRMS).

What it does:

AUBAGIO can alter the way the body's immune system works. AUBAGIO does not cure RRMS, but it can help decrease the number of attacks (relapses) that occur. AUBAGIO can help slow the build-up of physical problems (disability progression) that RRMS causes.

When it should not be used:

Do not take AUBAGIO if you:

- are allergic to teriflunomide, leflunomide or to any of the other ingredients in the formulation
- are taking a drug for rheumatoid arthritis with the medicinal ingredient leflunomide
- have severe liver problems
- have an infection
- are pregnant, suspect you may be pregnant or plan to get pregnant
- are a woman of childbearing potential not using reliable methods of birth control.
- are of childbearing age, until it is confirmed with a pregnancy test that you are not pregnant. This is done just before you begin treatment with AUBAGIO.
- have low platelets, low white blood cell counts, or uncontrolled infection. Low white blood cell counts may be caused by other things that affect the immune system such as:
 - immunodeficiency syndrome or AIDS
 - weakened bone marrow function or transplantation
 - treatments that can suppress the immune system such as
 - drugs used to treat cancer
 - other drugs used to treat MS

What the medicinal ingredient is: teriflunomide

What the nonmedicinal ingredients are:

corn starch, hydroxypropylcellulose, hypromellose, indigo carmine aluminum lake, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate, talc, and titanium dioxide.

What dosage forms it comes in:

Tablet 14 mg

WARNINGS AND PRECAUTIONS**LIVER DISORDER****BIRTH CONTROL, PREGNANCY and RISK OF BIRTH DEFECTS****Liver disorder**

AUBAGIO may cause liver disorders. Severe liver injury including fatal liver failure occurred rarely in patients treated with AUBAGIO. The risk for severe liver disorder may be increased if you take AUBAGIO when you already have liver disease or if you are taking other drugs that affect the liver.

Your doctor should do blood tests to check your liver function:

- within 6 months before you start taking AUBAGIO.
- every month, for 6 months after you start taking AUBAGIO.

Call your doctor right away if you experience any symptoms of liver disorder.

Birth control, Pregnancy and Risk of Birth Defects

Do not take AUBAGIO if you are pregnant. If used during pregnancy, AUBAGIO may cause major birth defects and even death to your baby. Pregnancy must be avoided by using effective birth control when a man or woman is on AUBAGIO. Continue birth control for two years after you stop taking AUBAGIO to make sure your blood levels of AUBAGIO are low enough. Your doctor can prescribe a medicine to help lower your blood levels of AUBAGIO more quickly. Your doctor can inform you when it is safe to get pregnant or to father a child.

If you are a **woman** of childbearing age, you should have a pregnancy test before you start taking AUBAGIO. If you become pregnant, are late starting your period or have any reason to suspect pregnancy while taking AUBAGIO or within 2 years after stopping it, tell your doctor right away.

Before you take AUBAGIO, tell your doctor or pharmacist about all your medical conditions, including if you:

- have liver problems.
- have high blood pressure
- have a fever or infection, or you are unable to fight infections
- had or now have blood or bone marrow problems
- have kidney problems
- had or now have tuberculosis
- have diabetes
- are older than 60 years
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed. It is not known if AUBAGIO passes into your breast milk. You and your doctor should decide if you will take AUBAGIO or breastfeed. You should not do both at the same time.

You should not receive certain types of vaccines (called “live attenuated vaccines”) during treatment with AUBAGIO. Check with your doctor before receiving any vaccination during treatment or after stopping AUBAGIO.

Pregnancy Registry: If you become pregnant while taking AUBAGIO or after you stop taking AUBAGIO, talk to your doctor about enrolling in the AUBAGIO Pregnancy Registry at 1-800-745-4447, option 2. The purpose of this registry is to collect information about the effect of AUBAGIO exposure during pregnancy.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with AUBAGIO:

- leflunomide, a medication for rheumatoid arthritis
- medicines that could raise your chance of getting infections, such as medicines to treat cancer or to control your immune system. **Ask your doctor or pharmacist for a list of these medicines if you are not sure**
- warfarin
- medicines used to treat diabetes, such as: repaglinide, pioglitazone, rosiglitazone, nateglinide
- oral contraceptives
- some medicines used to treat infections such as: cefaclor, penicillin G, ciprofloxacin, rifampin, zidovudine
- medicines used to lower blood cholesterol, such as: rosuvastatin, atorvastatin, simvastatin, pravastatin

- anti-inflammatory drugs, such as: indomethacin, ketoprofen, sulfasalazine
- diuretics (water losing pills), such as: furosemide
- some medicines to treat cancer such as: paclitaxel, methotrexate, mitoxantrone, topotecan, daunorubicin, doxorubicin
- duloxetine (anti-depressant); theophylline (asthma medicine); cimetidine (stomach acid medicine); tizanidine (muscle relaxant medicine)
- avoid drinking alcohol while taking AUBAGIO as it may cause liver problems.

PROPER USE OF THIS MEDICATION

- Follow your doctor’s instructions carefully. Do not take more than the recommended dose.
- Take AUBAGIO orally (by mouth) with or without food.
- Do not stop taking AUBAGIO without talking with your doctor first.

Usual Adult Dose: 1 tablet a day.

Missed dose:

If you missed a dose, take just the next following dose. Do not take a double dose to make up for a forgotten tablet.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- diarrhea, nausea, flu or sinus infection, upset stomach, abdominal pain
- rash
- abnormal liver tests
- hair thinning or loss

If any of these affects you severely, tell your doctor, nurse or pharmacist.

AUBAGIO can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

Deaths due to heart-related issues have occurred in patients treated with AUBAGIO.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Decreased White Blood Cells: infections, feeling unusually tired, fever, aches, pains and flu-like symptoms		√	
	High Blood Pressure: headaches, vision disorders, nausea and vomiting		√	
	Liver Disorder: Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite, weight loss, unusual tiredness.			√
Uncommon	Decreased Platelets: bruising, bleeding, feeling unusually tired and weakness		√	

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Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
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Uncommon	Heart Attacks: shortness of breath, chest pain, feeling of a rapid heart beat, light headedness, nausea, vomiting, anxiety			√
	Peripheral Neuropathy/ Carpal tunnel syndrome: numbness or tingling of hands or feet		√	
Rare	Interstitial Lung Disease: shortness of breath, trouble breathing, lasting cough		√	
Unknown	Allergic/ Hypersensitivity reaction Rash, itching, trouble breathing, swelling of the face, lips tongue or throat			√

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Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
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Unknown	Pancreatitis Severe pain in upper abdominal area which may spread to back, nausea, vomiting, fever			√
	Severe Skin Reactions: Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: any combination of itchy skin rash, redness, blistering and peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, with fever, chills, headache, cough, body aches or swollen glands, joint pain, yellowing of the skin or eyes, dark urine.			√

This is not a complete list of side effects. For any unexpected effects while taking AUBAGIO, contact your doctor or pharmacist.

HOW TO STORE IT

Store AUBAGIO between 15° to 30°C.

For blister card wallet, remove tablet only when ready to use.

Once the bottle is opened, the tablets must be used within 90 days.

Keep AUBAGIO and all medicines out of reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
 Health Canada
 Postal Locator 0701E
 Ottawa, Ontario
 K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at: **Error!** **Hyperlink reference not valid.** www.sanofigenzyme.ca or by contacting the sponsor, Sanofi Genzyme, a division of Sanofi-aventis Canada Inc. at: 1-855-671-2663

This leaflet was prepared by Sanofi Genzyme, a division of sanofi-aventis Canada Inc.

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