

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **AUBAGIO**[®]

Teriflunomide tablets

Read this carefully before you start taking **AUBAGIO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **AUBAGIO**.

Serious Warnings and Precautions

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 healthcare professional should do blood tests to check your liver function:

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

Call your healthcare professional right away if you experience any symptoms of liver disorder (see the **Serious side effects and what to do about them** table below for a list of symptoms).

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 healthcare professional can prescribe a medicine to help lower your blood levels of AUBAGIO more quickly. Your healthcare professional 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 healthcare professional right away.

What is AUBAGIO used for?

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

How does AUBAGIO work?

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.

What are the ingredients in AUBAGIO?

Medicinal ingredients: teriflunomide

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

AUBAGIO comes in the following dosage forms:

Tablet; 14 mg

Do not use AUBAGIO if:

- you are allergic to teriflunomide, leflunomide or to any of the other ingredients in the formulation
- you are taking a drug for rheumatoid arthritis with the medicinal ingredient leflunomide
- you have severe liver problems
- you are suffering from a serious infection
- you are pregnant, suspect you may be pregnant or plan to get pregnant
- you are a woman of childbearing potential not using reliable methods of birth control
- you are of childbearing age, until it is confirmed with a pregnancy test that you are not pregnant
- you have low platelets, or 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

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AUBAGIO. Talk about any health conditions or problems you may have, including if you:

- have liver problems.
- have high blood pressure
- have a fever or infection, or you are unable to fight infections
- have low protein levels in your blood
- have or have ever had blood or bone marrow problems
- have kidney problems
- have or have ever had tuberculosis
- have diabetes
- are older than 60 years
- are breastfeeding or plan to breastfeed. You and your healthcare professional should decide if you will take AUBAGIO or breastfeed. You should not do both at the same time.
- have a condition that affects the skin or nails called psoriasis
- have an allergy to lactose or a rare hereditary problem of galactose intolerance, total lactose deficiency or glucose-galactose malabsorption. AUBAGIO contains lactose.
- are going to receive a vaccine. You should not receive a “live attenuated vaccine” during treatment with AUBAGIO. Talk to your healthcare professional before receiving any vaccinations during or after treatment

Other warnings you should know about:

Pregnancy: AUBAGIO may harm your unborn baby. Before you start treatment with AUBAGIO, your healthcare professional may require you to do a pregnancy test to make sure you are not pregnant. You must use a reliable form of birth control while taking AUBAGIO. Do not become pregnant during treatment.

Pregnancy Registry: Contact your healthcare professional right away if you:

- become pregnant,
- suspect you may be pregnant while taking AUBAGIO,
- become pregnant within two years after you stop taking AUBAGIO.

A Pregnancy Registry Study has been established to collect information about the effect of teriflunomide exposure during pregnancy. Your healthcare professional can enroll you in the Pregnancy Registry Study, or you may enroll yourself in the Pregnancy Registry Study by calling 1-877-311-8972.

Use in Males: If your partner can get pregnant, make sure to use a reliable form of birth control when you are taking AUBAGIO. If you wish to father a child or donate sperm, talk to your healthcare professional about stopping your treatment.

Blood Tests: Your healthcare professional should do blood tests before starting treatment with AUBAGIO and while you are taking it. These tests will monitor:

- blood pressure
- complete blood cell count
- liver enzyme levels

AUBAGIO may cause your test results to look abnormal. Your healthcare professional will interpret the results.

Interstitial Lung Disease (ILD): A condition called ILD has been reported with AUBAGIO. If you have a history of ILD, you are at higher risk of developing ILD again. If you already have ILD, AUBAGIO may worsen the symptoms. ILD can be a fatal disorder and can happen at any time during your treatment. Talk to your healthcare professional right away if you experience:

- persistent cough
- shortness of breath with or without fever

AUBAGIO can cause serious side effects, including:

- Pancreatitis (inflammation of the pancreas)
- Peripheral Neuropathy (damage to nerves)
- Severe skin reactions such as Stevens - Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

Accelerated Elimination Procedure: It can take 8 months to 2 years to fully remove teriflunomide from your system. If you need to stop taking AUBAGIO, your healthcare professional may talk to you about undergoing an accelerated elimination procedure to remove teriflunomide from your body faster.

Tell your healthcare professional about all the medicines you take, including any drugs, 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 healthcare professional 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.
- other medicines that can potentially harm the liver

How to take AUBAGIO:

- Follow your healthcare professional’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 healthcare professional first.

Usual dose:

1 tablet a day.

Overdose:

If you think you, or a person you are caring for, have taken too much **AUBAGIO**, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, just take your next dose as planned. Do not take a double dose to make up for a forgotten tablet.

What are possible side effects from using AUBAGIO?

These are not all the possible side effects you may have when taking AUBAGIO. If you experience any side effects not listed here, tell your healthcare professional.

- diarrhea, nausea, flu or sinus infection, upset stomach, abdominal pain
- rash
- abnormal liver tests
- hair thinning or loss
- cold sores
- toothache
- shortness of breath
- frequent urination
- having your period for longer than 7 days
- sore muscles
- weight loss

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Decreased White Blood Cells: infections, fatigue, fever, aches, pains and flu-like symptoms		√	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness		√	

Serious side effects and what to do about them			
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or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations			
Liver Disorder: yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite			√
UNCOMMON			
Decreased Platelets: bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		√	
Severe Heart Problems: pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat. Deaths due to heart-related issues have occurred in patients treated with AUBAGIO.			√
Peripheral Neuropathy/ Carpal tunnel syndrome: numbness or tingling of hands or feet		√	
RARE			
Interstitial Lung Disease (disease that inflames or scars lung tissue): shortness of breath when resting that gets worse with exertion, trouble breathing, lasting cough		√	
UNKNOWN			
Allergic Reaction: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat			√
Colitis (chronic digestive disease): diarrhea with blood or pus, abdominal pain, cramping, rectal pain or bleeding, weight loss, fatigue		√	
Pancreatitis (inflammation of the			√

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pancreas): upper abdominal pain, fever, fast heart beat, nausea, vomiting, tenderness when touching the abdomen			
Psoriasis (chronic skin disease on the skin or nails): red patches of skin covered with thick, silvery scales, dry cracked skin that may bleed, itching, burning or soreness, swollen and stiff joints		√	
Severe Skin Reactions: Fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes or genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Store AUBAGIO between 15°C 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 out of reach and sight of children.

If you want more information about AUBAGIO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.sanofi.ca, or by calling 1-855-671-2663.

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

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