

PACKAGE LEAFLET: INFORMATION FOR THE USER

AUBAGIO® 14 mg

film-coated tablets

teriflunomide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Aubagio is and what it is used for
2. What you need to know before you take Aubagio
3. How to take Aubagio
4. Possible side effects
5. How to store Aubagio
6. Contents of the pack and other information

1. WHAT AUBAGIO IS AND WHAT IT IS USED FOR

What Aubagio is

Aubagio contains the active substance teriflunomide which is an immunomodulatory agent and adjusts the immune system to limit its attack on the nervous system.

What Aubagio is used for

Aubagio is used in adults to treat relapsing remitting multiple sclerosis (MS).

What multiple sclerosis is

MS is a long-term illness that affects the central nervous system (CNS). The CNS is made up of the brain and spinal cord. In multiple sclerosis, inflammation destroys the protective sheath (called myelin) around the nerves in the CNS. This loss of myelin is called demyelination. This stops nerves from working properly.

People with relapsing form of multiple sclerosis will have repeated attacks (relapses) of physical symptoms caused by their nerves not working properly. These symptoms vary from patient to patient but usually involve:

- difficulty walking
- vision problems
- balance problems.

Symptoms may disappear completely after the relapse is over, but over time, some problems may remain between relapses. This can cause physical disabilities that may interfere with your daily activities.

How Aubagio works

Aubagio helps to protect against attacks on the central nervous system by the immune system by limiting the increase of some white blood cells (lymphocytes). This limits the inflammation that leads to nerve damage in MS.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AUBAGIO

Contraindications:

Do not take Aubagio:

- if you are allergic to teriflunomide or any of the other ingredients of this medicine (listed in section 6),
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking teriflunomide or leflunomide,
- if you have severe liver problems,
- if you are pregnant, think you may be pregnant, or are breast-feeding,
- if you suffer from a serious problem which affects your immune system e.g. acquired immunodeficiency syndrome (AIDS),
- if you have a serious problem with your bone marrow, or if you have low numbers of red or white cells in your blood or a reduced number of blood platelets,
- if you are suffering from a serious infection,
- if you have severe kidney problems which require dialysis,
- if you have very low levels of proteins in your blood (hypoproteinaemia), If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Aubagio if:

- you have liver problems and/or if you drink large amounts of alcohol. Your doctor will carry out blood tests before and during treatment to check how well your liver is working. If your test results show a problem with your liver, your doctor may stop your treatment with Aubagio. Please read section 4.
- you have high blood pressure (hypertension) whether it is controlled with medicines or not.
- Aubagio can cause an increase in blood pressure. Your doctor will check your blood pressure before the start of treatment and regularly thereafter. Please read section 4.
- you have an infection. Before you take Aubagio, your doctor will make sure you have enough white blood cells and platelets in your blood. As Aubagio decreases the number of white cells in the blood this may affect your ability to fight the infection. Your doctor may do blood tests to check your white blood cells if you think you have an infection. Please read section 4.
- you have severe skin reactions.
- you have respiratory symptoms.
- you have weakness, numbness and pain in the hands and feet.
- you are going to have a vaccination.
- you take leflunomide with Aubagio.
- you are switching to or from Aubagio.
- you are due to have a specific blood test (calcium level). Falsely low levels of calcium can be detected.

Respiratory reactions

Tell your doctor if you have unexplained cough and dyspnoea (shortness of breath). Your doctor may perform additional tests

Children and adolescents

Aubagio should not be used in children and adolescents under 18 years of age.

Other medicines and Aubagio

Tell your your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- leflunomide, methotrexate and other medicines that affect the immune system (often called immunosuppressants or immunomodulators)
- rifampicin (a medicine used to treat tuberculosis and other infections)
- carbamazepine, phenobarbital, phenytoin for epilepsy St John's wort (a herbal medicine for depression)
- repaglinide, pioglitazone, nateglinide, or rosiglitazone for diabetes
- daunorubicin, doxorubicin, paclitaxel, or topotecan for cancer
- duloxetine for depression, urinary incontinence or in kidney disease in diabetics
- alosetron for the management of severe diarrhoea
- theophylline for asthma
- tizanidine, a muscle relaxant
- warfarin, an anticoagulant used to make the blood thinner (i.e. more fluid) in order to avoid blood clots
- oral contraceptives (containing ethinylestradiol and levonorgestrel)
- cefaclor, benzylpenicillin (penicillin G), ciprofloxacin for infections
- indometacin, ketoprofen for pain or inflammation
- furosemide for heart disease
- cimetidine for reducing gastric acid
- zidovudine for HIV infection
- rosuvastatin, simvastatin, atorvastatin, pravastatin for hypercholesterolemia (high cholesterol)
- sulfasalazine for inflammatory bowel disease or rheumatoid arthritis
- cholestyramine for high cholesterol or relief from itching in liver disease
- activated charcoal to reduce absorption of medicines or other substances

Pregnancy and breast-feeding

Do not take Aubagio if you are, or think you may be **pregnant**. If you are pregnant or become pregnant while taking Aubagio, the risk of having a baby with birth defects is increased. Women of childbearing potential must not take this medicine without using reliable contraceptive measures.

Tell your doctor if you plan to become pregnant after stopping treatment with Aubagio, as you need to ensure that most of this medicine has left your body before trying to become pregnant. The elimination of the active substance may take up to 2 years to occur naturally. The time can be reduced to a few weeks by taking certain medicines which speed up removal of Aubagio from your body.

In either case it should be confirmed by a blood test that the active substance has been sufficiently removed from your body and you need confirmation from your treating physician that the blood level of Aubagio is low enough to allow you to become pregnant.

For further information on the laboratory testing please contact your doctor.

If you suspect that you are pregnant while taking Aubagio or in the two years after you have stopped treatment, you must discontinue Aubagio and contact your doctor **immediately** for a pregnancy test. If the test confirms that you are pregnant, your doctor may suggest treatment with certain medicines to remove Aubagio rapidly and sufficiently from your body, as this may decrease the risk to your baby.

Contraception

You must use an effective method of contraception during and after treatment with Aubagio. Teriflunomide remains in your blood for a long time after you stop taking it. Continue to use effective contraception after you stop treatment.

- Do this until the levels of Aubagio in your blood are low enough - your doctor will check this.
- Talk with your doctor about the best method of contraception for you and any potential need for contraception change.

Do not take Aubagio when you are breast-feeding, as teriflunomide passes into the breast milk.

Driving and using machines

Aubagio might make you feel dizzy which may impair your ability to concentrate and react. If you are affected, do not drive or use machines.

Aubagio contains lactose

Aubagio contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Aubagio contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE AUBAGIO

Treatment with Aubagio will be overseen by a doctor who is experienced in the treatment of multiple sclerosis.

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is one 14 mg tablet daily.

Route/method of administration

Aubagio is for oral use. Aubagio is taken every day as a single dose at any time of the day. You should swallow the tablet whole with some water. Aubagio may be taken with or without food.

If you take more Aubagio than you should

If you have taken too much Aubagio, call your doctor straight away. You may experience side effects similar to those described in section 4 below.

If you forget to take Aubagio

Do not take a double dose to make up for a forgotten tablet. Take your next dose at the scheduled time.

If you stop taking Aubagio

Do not stop taking Aubagio or change your dose without talking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Serious side effects

Some side effects could be or could become serious, if you experience any of these, **tell your doctor immediately**.

Uncommon (may affect up to 1 in 100 people)

- inflammation of the pancreas which might include symptoms of pain in the abdominal area, nausea, or vomiting
- allergic reactions which might include symptoms of rash, hives, swelling of lips, tongue or face or sudden difficulty breathing.
- severe skin reactions which might include symptoms of skin rash, blistering, fever, or ulcers in your mouth
- severe infections or sepsis (a potentially life-threatening type of infection) which might include symptoms of high fever, shaking, chills, reduced urine flow, or confusion
- inflammation of the lungs which might include symptoms of shortness of breath or persistent cough

Not known (frequency cannot be estimated from the available data):

- serious liver disease which might include symptoms of yellowing of your skin or the whites of your eyes, darker urine than normal, unexplained nausea and vomiting, or abdominal pain

Other side effects can occur with the following frequencies:

Very common (may affect more than 1 in 10 people)

- Headache
- Diarrhoea, feeling sick
- Increase in ALT (increase in blood levels of certain hepatic enzymes) shown in tests
- Hair thinning

Common (may affect up to 1 in 10 people)

- Influenza, upper respiratory tract infection, urinary tract infection, bronchitis, sinusitis, sore throat and discomfort when swallowing, cystitis, gastroenteritis viral, oral herpes, tooth infection, laryngitis, fungal infection of the foot
- Laboratory values: a decrease in the number of red blood cells (anaemia), changes in liver and white blood cell test results (see section 2), as well as elevations in a muscle enzyme (creatine phosphokinase) have been observed.
- Mild allergic reactions
- Feeling anxious
- Pins and needles, feeling weak, numb, tingling or pain in the lower back or leg (sciatica); feeling
- numb, burning, tingling or pain in the hands and fingers (carpal tunnel syndrome)
- Feeling your heartbeat
- Increase in blood pressure
- Being sick (vomiting), toothache, upper abdominal pain
- Rash, acne
- Pain of the tendons, joints, bones, muscle pain (musculoskeletal pain),
- Needing to urinate more often than usual
- Heavy periods
- Pain
- Lack of energy or feeling weak (asthenia)
- Weight loss

Uncommon (may affect up to 1 in 100 people)

- Decrease in the number of blood platelets (mild thrombocytopenia)
- Increased feeling or sensitivity, especially in the skin; stabbing or throbbing pain along one or more
- nerves, problems in the nerves of the arms or legs (peripheral neuropathy)
- Nail disorders, severe skin reactions
- Post-traumatic pain
- Psoriasis
- Inflammation of mouth/lips
- Abnormal levels of fats (lipids) in the blood
- Inflammation of the colon (colitis)

Rare (may affect up to 1 in 1,000 people)

Inflammation or injury of the liver

Not known (frequency cannot be estimated from the available data)

Respiratory hypertension

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AUBAGIO

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and wallet after “EXP”. The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Aubagio 14 mg, film-coated tablets contains

- The active substance is teriflunomide.
- Each tablet contains 14 mg of teriflunomide.
- The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, sodium starch glycolate (Type A), hydroxypropylcellulose, magnesium stearate, hypromellose, titanium dioxide (E171), talc, macrogol 8000, indigo carmine aluminum lake (E132) (see section 2 “Aubagio contains lactose”).

What Aubagio 14 mg, film-coated tablets looks like and contents of the pack

Aubagio 14 mg film-coated tablets (tablets) are pale blue to pastel blue, pentagonal film-coated tablets with imprint on one side ('14') and engraved with a corporate logo on the other side.

Aubagio is available in cardboard cartons containing:

- 14, 28, 84 and 98 tablets in wallet packs with integrated aluminium blisters;
- 10x1 tablet in all aluminium perforated unit-dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Sanofi Winthrop Industrie
82 avenue Raspail
94250 Gentilly
France

Manufacturer:

Opella Healthcare International SAS
56, Route de Choisy
60200
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