

AUBAGIO 14mg Film-coated Tablets

Teriflunomide 14 mg

What is in this leaflet

1. What AUBAGIO is used for
2. How AUBAGIO works
3. Before you use AUBAGIO
4. How to use AUBAGIO
5. While you are using AUBAGIO
6. Side effects
7. Storage and Disposal of AUBAGIO
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial number

What AUBAGIO is used for

AUBAGIO is used for the treatment of adult patients with relapsing remitting multiple sclerosis (MS).

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.

Before you use AUBAGIO

When you must not take it

Do not take AUBAGIO if you:

- are allergic to the active substance or any of the ingredients in this medicine (listed in *Product Description*)
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking teriflunomide or leflunomide
- have severe liver problems
- are **pregnant**, think you may be pregnant, or are breast-feeding
- suffer from a serious problem which affects your immune system (e.g. AIDS)
- have serious problems 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
- are suffering from a serious infection
- have severe kidney problems which require dialysis

- have very low levels of protein in your blood (hypoproteinaemia)

If you are not sure, talk to your doctor or pharmacist before taking AUBAGIO.

Before you start to take it

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.
- 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 regularly during treatment.
- you are going to have a vaccination.
- you have an infection. Before you take AUBAGIO, your doctor will make sure you have enough white blood cells and platelet in your blood. As AUBAGIO decreases the number of white blood 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 any infection. Herpes virus infections, including oral herpes or herpes zoster (shingles) may occur with teriflunomide treatment. In some cases, serious complications have occurred. You should inform your doctor immediately if you suspect you have any symptoms of herpes virus infections.
- you have severe skin reactions.
- you have respiratory symptoms
- you have weakness, numbness and pain in the hands and feet
- you take leflunomide with AUBAGIO.
- you are switching to or from AUBAGIO.
- you are lactose intolerant.
- you are due to have a specific blood test (calcium level). Falsely low levels of calcium can be detected.

Talk to your doctor or pharmacist:

- if you develop skin ulcers or experience impaired wound healing while being treated with AUBAGIO.
- if you will have or have had recent major surgery, or if you still have an unhealed wound following surgery as AUBAGIO may impair wound healing.

Respiratory reactions

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

If the above applies to you (or if you are not sure), talk to your doctor or pharmacist before taking AUBAGIO.

Taking other medicines

Tell 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 diarrhea
- theophylline for asthma
- tizanidine, a muscle relaxant
- warfarin, an anticoagulant used to make blood thinner in order to avoid blood clots
- oral contraceptives (containing ethinylestradiol and levonorgestrel)
- cefaclor, benzylpenicillin (penicillin G), ciprofloxacin for infections

AUBAGIO 14mg Film-coated Tablets

Teriflunomide 14 mg

- indomethacin, 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

Children and adolescent

AUBAGIO should not be used in children and adolescent under 18 years of age. This is because the effects of the medicine in this age group are not known.

How to use AUBAGIO

Treatment with AUBAGIO will be overseen by a doctor who is experienced in the treatment of MS.

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

How much to take

The recommended dose is one film-coated tablet (14 mg) daily.

When to take it

AUBAGIO is for oral use. AUBAGIO is taken every day as a single daily dose at any time of the day.

You should swallow the tablet whole with some water.

AUBAGIO may be taken with or without food.

How long to take it

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

If you forget to take it

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

If you take too much (overdose)

If you have taken too much AUBAGIO, call your doctor straight away. You may experience side effects similar to those described in section *Side Effects*.

While you are using AUBAGIO

Things you must do

Call your doctor right away if you have any of the serious side effects.

Things you must not do

Do not stop taking AUBAGIO or change your dose without checking with your doctor.

Things to be careful of

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 AUBAGIO 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 the AUBAGIO has left your body before trying to become pregnant. This drug elimination may take up to 2 years to occur naturally. The time can be reduced to 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 AUBAGIO 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 you are pregnant while taking AUBAGIO or in the two years after you have stopped treatment, you must contact your doctor **immediately** for 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 your 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 makes 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 for some sugars, talk to 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'.

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

Tell your doctor straight away, if you notice any of the following serious side effects:

- allergic reactions which might include symptoms of rash, hives, swelling of lips, tongue or face or sudden difficulty breathing

AUBAGIO 14mg Film-coated Tablets

Teriflunomide 14 mg

- severe skin reactions which might include symptoms of skin rash, blistering, 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
- serious liver disease which might include symptoms of yellowing of your skin or the whites of your eyes, darker urine than normal or unexplained nausea and vomiting, or abdominal pain
- inflammation of the lungs which might include symptoms of shortness of breath or persistent cough
- inflammation of the pancreas which might include symptoms of severe pain in the upper abdominal area that may also be felt in your back, nausea, or vomiting
- 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
- 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)

- Severe infections (including sepsis)
- Severe allergic reactions (including anaphylaxis)
- Pulmonary reaction (interstitial lung disease, ILD)
- Inflammation of the liver, pancreas, or mouth/lips
- Abnormal levels of fats (lipids) in the blood
- Psoriasis
- Pulmonary hypertension

These are not all the possible side effects of AUBAGIO. For more information, ask your doctor or pharmacist.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of AUBAGIO

- Storage

Store below 30°C.

Keep this medicine out of the reach of children.

- Disposal

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 to protect the environment.

Product description

What AUBAGIO looks like

AUBAGIO 14 mg film-coated tablets are pale blue to pastel blue, pentagonal film-coated tablets with imprint on one ('14') and engraved with a corporate logo on the other side. AUBAGIO is available in cardboard cartons containing 28 tablets in wallet packs with integrated aluminium blister.

What AUBAGIO contains:

- *Active ingredient*
Teriflunomide

- *Inactive ingredients*

Lactose monohydrate, maize starch, microcrystalline cellulose, sodium starch glycolate (Type A), hydroxypropylcellulose, magnesium stearate, hypromellose, titanium dioxide (E171), talc, macrogol 8000, indigo carmine aluminium lake (E132).

Registration Number:
MAL15045075AZ

Other side effects include

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

- headache
- diarrhea, feeling sick
- increase ALT (increase in blood levels of certain hepatic enzyme) shown in tests
- hair thinning

Common side effects (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, tooth infection, laryngitis, fungal infection of the foot
- Herpes virus infections, including oral herpes and herpes zoster (shingles) with symptoms such as blisters, burning, itching, numbness or pain of the skin, typically on one side of the upper body or face, and other symptoms, like fever and weakness
- laboratory values: a decrease in the number of red blood cells (anaemia), changes in liver and white blood cell test results, as well as elevations in a muscle enzyme (creatine phosphokinase) have been observed.
- mild allergic reactions
- feeling anxious

AUBAGIO 14mg Film-coated Tablets

Teriflunomide 14 mg

**Manufacturer and Product
Registration Holder**

Manufacturer:

Opella Healthcare International SAS
56 Route de Choisy
60200 Compiègne
France

Product Registration Holder:

Sanofi-aventis (Malaysia) Sdn. Bhd.
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