

Information Sheet

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Aubagio

What is Aubagio?

Aubagio is a Disease Modifying Treatment (DMT) for relapsing remitting MS. You have fewer relapses than you might have had with no treatment and any relapses you do have should be less severe. In clinical trials people taking Aubagio had in the range of 30% fewer relapses than people taking placebo. In clinical trials, MRI scans showed people taking Aubagio had fewer, smaller or no new areas of active MS (lesions). Aubagio also slows down the build-up of disability associated with MS.

The active substance in Aubagio is teriflunomide.

Who is prescribed Aubagio?

Aubagio is prescribed to adults with relapsing remitting MS.

Contraindications

It's important that you tell your MS team if you have any health problems or are taking other medicines. Aubagio may not be appropriate if you have existing medical conditions including: severe liver problems, serious problems affecting the immune system (eg AIDS) and significant problems affecting bone marrow or reduced blood cell counts (eg anaemia, leucopenia, neutropenia or thrombocytopenia).

Assessment before treatment

Before starting Aubagio, you should have blood tests to measure blood cell counts and check liver function. Blood pressure will also be checked. Pregnancy must be excluded before start of treatment.

Assessment during treatment

Once you've started treatment you'll have blood tests to monitor liver function every 2 weeks for the first 6 months and every 8 weeks thereafter or as indicated by clinical signs and symptoms such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine.

If your doctor prescribes Aubagio, a home phlebotomy (blood testing) service is available for 6 months. Information on this service is available from your physician or MS Nurse.

Blood pressure and blood cell counts will also be monitored periodically during treatment.

How is it administered?

Aubagio is an oral tablet taken once daily.

How does Aubagio help my MS?

Aubagio reduces the number of MS relapses by up to 36%. 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.

What are the side effects?

Common side effects of treatment include feeling sick, diarrhoea and hair thinning which can occur during the first few months of treatment but generally improve in following months. Increased blood levels of liver enzymes can also occur.

Common side effects (affecting more than 1 person in 100)

- increased levels of liver enzymes
- nausea and diarrhoea
- hair thinning and loss
- urinary tract infection
- inflammation of the nose and throat
- influenza
- pins and needles
- upper respiratory tract infections
- decrease in white blood cells (neutropenia)
- mild allergic reactions
- anxiety
- nerve pain
- decrease in red blood cells (anaemia)
- increase in blood pressure
- rash
- musculoskeletal pain

Less common side effects (affecting less than 1 person in 100)

- decrease in blood platelets (thrombocytopenia)
- peripheral neuropathy

Do I continue to take Aubagio if I am thinking of becoming pregnant or breastfeeding?

Teriflunomide is contradicted in pregnancy. There is a limited amount of data from the use of teriflunomide in pregnant women. Studies in animals have shown reproductive toxicity. Teriflunomide may cause serious birth defects when administered during pregnancy.

Women of childbearing potential have to use effective contraception during treatment and after treatment as long as teriflunomide plasma concentration is above 0.02 mg/l. During this period women should discuss any plans to stop or change contraception with the treating physician (Aubagio SPC, 2015).

Women who are taking Aubagio who have any reason to suspect pregnancy must notify their physician immediately for pregnancy testing. For women receiving teriflunomide treatment who wish to become pregnant, the medicine should be stopped and an accelerated elimination procedure is recommended in order to more rapidly achieve concentration below 0.02 mg/l.

If accelerated elimination procedure is not used, teriflunomide plasma levels can be expected to be above 0.02 mg/l for an average of 8 months, however in some patients it may take up to two years to reach plasma concentration below 0.02 mg/l.

Aubagio research

Three main studies have provided the evidence to support approval of Aubagio for multiple sclerosis:

- **TEMESO - Aubagio compared to placebo**
TEMESO was a two year, double-blind study of 1088 people with relapsing remitting MS, comparing two doses of Aubagio with placebo. Compared to placebo, the drug reduced the number of relapses in one year by 35.1%. The licensed dose also reduced disability progression by 29.8% compared to placebo.
- **TOWER - Aubagio compared to placebo**
TOWER tested two different doses of Aubagio or placebo for at least 48 weeks in 1169 people with relapsing remitting MS. Compared to placebo, the higher dose reduced the number of relapses in one year by 36%. The licensed dose of Aubagio reduced the risk of disability progression by 31.5%.
- **TENERE - Aubagio compared to Rebif**
This study compared two doses of Aubagio with Rebif (interferon beta 1a) in 324 people over two years. The main measure of the study was the time to first relapse or stopping treatment for any reason. No statistical superiority

was observed between Aubagio and SC IFN β -1a in time to failure. There was a change in fatigue score measure for SC IFN β 1a (secondary endpoint) in favour of Aubagio. Significant improvement in global satisfaction was observed for Aubagio v SC IFN β 1a. This improvement was primarily related to better patient scores in side effects and convenience.

When was Aubagio made available in Ireland?

Aubagio was authorised for use in Ireland in 2014. It is reimbursed under the High-Tech Scheme, so is available free of charge to those on the Long Term Illness Scheme.

Sources:

This information was adapted from <https://www.mstrust.org.uk/a-z/aubagio-teriflunomide> and from Ms Ireland's Access to Medicines Campaign Handbook - <http://www.ms-society.ie/pages/living-with-ms/information-centre/our-publications>

<http://www.medicines.ie/medicine/16050/SPC/AUBAGIO+14+mg+film-coated+tablets/>

Disclaimer

MS Ireland provides information to the MS community on an array of topics associated with MS. This information is for reference purposes only and medical advice should always be sought before any treatment or intervention is tried. This information sheet is not intended as a substitute for advice from a medical professional.