Teriflunomide for the treatment of multiple sclerosis

What is Teriflunomide?
Teriflunomide (also called Aubagio) is a disease modifying therapy (DMT) used to treat relapsing remitting multiple sclerosis (RRMS). NICE (2014) has recommended this treatment for patients with RRMS who have had two clinically significant relapses in the last two years. It can be used in patients who have not previously had a DMT, or who are already taking a DMT but continuing to have relapses despite treatment. It has the advantage of being a tablet, unlike the other treatments used in this form of MS, which are mostly given as an injection. As the only tablet treatment currently available as a first line treatment for RRMS, it provides a new option.

How effective is it?
In trials, Teriflunomide reduced the number of relapses (attacks) by about a third (the same amount as the alternative injectable treatments, Interferon and Copaxone). It also had a slight effect in reducing the accumulation of disability. A study directly comparing it against Rebif (an interferon), suggested the two drugs were similarly effective and tolerated.

Why should I consider Teriflunomide?
Its major benefit is that it is given as a tablet rather than an injection.

How does it work?
In multiple sclerosis, the immune system causes inflammation in the brain and spinal cord. As with many MS therapies, Teriflunomide seems to work by making the immune system less active, by limiting the increase of some white blood cells.

How is it given?
Teriflunomide is given as a daily tablet.

Other medicines and Teriflunomide
Teriflunomide can interfere with the effects of a number of medications, and other medications can reduce the effectiveness of Teriflunomide. These “interactions” can occur with both prescribed medication, but also medications that are obtained without a prescription. Before starting Teriflunomide, we will need to know what medication you are taking.
Once you have started, you will need to tell your GP and pharmacist that you are taking teriflunomide before starting any other medication, to ensure it is safe to take these medications together.

**What are the risks of treatment with Teriflunomide?**

While it has the convenience of being a tablet rather than injection, much more monitoring is required with Teriflunomide than with the injectable alternatives (interferon and copaxone). There are also a number of additional risks associated with this treatment which is why more careful monitoring is required. This is why we ask for your written consent to start treatment with Teriflunomide. In addition to this information sheet, you will be provided with an information sheet provided by Genzyme, the manufacturer or Teriflunomide. These issues and risks are summarised below.

**Is there any reason why I might not be able to have Teriflunomide?**

Do not take Teriflunomide if you:

- have severe liver problems
- are pregnant, think you might be pregnant, or are breast feeding (see below)
- have a serious problem that effects your immune system (e.g. AIDS)
- have a serious problem with your bone marrow
- are suffering from any severe infection
- have significant kidney problems

**Pregnancy and breast feeding**

There is a very real concern based on studies in animals that Teriflunomide is harmful to pregnancy. It is essential that patients on Teriflunomide do not become pregnant. Women of child bearing age will normally be asked to perform a pregnancy test to confirm they are not pregnant before starting teriflunomide. It is important to ensure that adequate contraception is continued while on Teriflunomide, and for up to two years after discontinuing treatment (see below).

Teriflunomide is passed into breast milk, so women on Teriflunomide will not be able to breast feed.

**What if I think I might have become pregnant?**

If your period is late, or you have other reasons to believe you might be pregnant, an urgent pregnancy test must be performed. If this is positive, you will need to stop Teriflunomide immediately. You will also need to contact your GP, to prescribe a treatment that can flush the Teriflunomide out of your body rapidly, to limit the potential harm it can cause. This treatment takes 11 days, after which you would have a blood test at the hospital to ensure the Teriflunomide has been removed from your blood. More details are enclosed in the package leaflet (Information for the Patient).
What are the side effects?

Some side effects are common, others much rarer but more serious.

**Common/very common side effects** (may affect one in 10 people or more) include:

- Infection (such as chest infection, urinary tract infection)
- Pins and needles
- Diarrhoea, feeling sick
- Inflammation of the liver, picked up on blood tests
- Hair thinning
- Increase in blood pressure
- Allergic reaction
- Pain
- Weight loss

**Serious side effects**

Tell your GP straight away if you notice any of the following:

- Yellowing of the skin or whites of your eyes, darker urine than normal or unexplained nausea and vomiting (these may be signs of a liver problem and you will need a blood test).
- Infection, this may include flu, throat infection, urine infection, diarrhoea, cold sores (oral herpes). Tell your doctor if you notice any of these side effects.

How will I be monitored while on Teriflunomide?

Unlike Interferon and Copaxone, much closer monitoring is required with Teriflunomide. This will include:

- GP practice visit to have blood tests every two weeks for the first six months of treatment. This is to ensure your liver does not become inflamed on treatment, and then every eight weeks after six months
- Checking your blood count before treatment, then at the hospital at three months, and then every six months.
- Checking your blood pressure before starting treatment, at the hospital visit, at three and six months.

What happens if I need to stop teriflunomide?

There are a numbers of reasons why you might need to stop Teriflunomide. If your walking gradually deteriorates (suggesting you have developed secondary progressive MS) we will need to stop treatment, as it is only used in patients with RRMS. If it does not reduce the number of attacks, we will need to consider alternative treatment.
Women who decide they want to become pregnant, will need to stop treatment, and either wait up to two years before becoming pregnant (the time it takes for the drug to leave the body), or take the course of treatment to wash the drug away more quickly.

If you have any further questions please contact the Multiple Sclerosis Nurses: 01223 257160

We are now a smoke-free site: smoking will not be allowed anywhere on the hospital site.
For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Help with this leaflet:

If you would like this information in another language, large print or audio, please ask the department where you are being treated, to contact the patient information team: patient.information@addenbrookes.nhs.uk.

Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

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