

### **For female patients including girls and their parents/ caregivers**

- Teriflunomide must not be used in pregnancy or in women of child-bearing potential if they are not using effective contraception because it can cause serious birth defects.
- Do not start teriflunomide when you are pregnant, or you think you may be pregnant. Your doctor may ask you to do a pregnancy test to make sure.
- Your doctor will provide counselling on the potential risks in case of pregnancy and on the need for effective contraception.
- You must use effective contraception during and after treatment with teriflunomide. Tell your doctor if you want to change your method of contraception or plan to become pregnant after stopping treatment with Teriflunomide. You should also discuss with your doctor if you plan to or are breastfeeding.

- If you suspect that you are pregnant while taking Teriflunomide or in the two years after you have stopped treatment, you must stop treatment with teriflunomide 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 speed up the removal of teriflunomide from your body, as this may decrease the risk to your baby.
- The parents or carers of girls should contact their daughter's doctor when they have their first period so that she can be counselled on the risk of birth defects during pregnancy and given advice on starting to use appropriate contraception.

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**accord**

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## **Teriflunomide Accord**

Patient's name:	
Date teriflunomide first prescribed:	
Hospital:	
Name of neurologist:	
Emergency phone number for neurologist:	

### **For further information, please contact:**

Accord Healthcare by Tel: 0044 1271 385 257 or by emailing: [medinfo@accord-healthcare.com](mailto:medinfo@accord-healthcare.com)

## PATIENT CARD:

**This patient card provides important information on the risks of Teriflunomide Accord.**

**Please keep it in a safe place and show this card to any doctor or healthcare professional involved in your medical care (e.g. in case of an emergency).**

**You should also read the patient information leaflet for further information.**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet. You can also report side effects directly to HPRA Pharmacovigilance; [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

Side effects should also be reported to Accord by calling 0044 1271 385 257 or by emailing: [medinfo@accord-healthcare.com](mailto:medinfo@accord-healthcare.com)

### **Important side effects**

Teriflunomide reduces the activity of the immune system (immunomodulator). In some people, teriflunomide can cause liver damage (hepatitis) and it may also reduce the production of white blood cells that fight infection (neutrophils) and platelets that are involved in blood clotting. Your liver function tests and blood pressure should be checked regularly during teriflunomide treatment and your full blood count should be checked if necessary. These tests should also be checked before starting treatment.

### **If you have any of the following side effects, please contact your doctor immediately:**

- Yellow skin or yellowing of the whites of your eyes (jaundice), unexplained nausea or vomiting, abdominal pain or darker urine than normal. These are the symptoms of a liver problem;
- Signs of an infection including fever, shivering, pain on passing urine or confusion.