

For SANOFI Pharmacovigilance center, please contact: +966-544-284-797 E-mail: ksa_pharmacovigilance@sanofi.com

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The National Pharmacovigilance Centre - Saudi Food and Drug Authority (SFDA)

In case of any drug related adverse events, please contact:



Treating doctor's phone number:

Treating doctor's name:

Centre name:

Date Terflonamide first prescribed:

Patient's name:

Aubagio (Terflonamide) PATIENT CARD

This Patient Card contains **important safety information** you need to be aware of when receiving treatment with Terflonamide . Please refer to patient leaflet for complete information.



General guidance

Please show this card to any doctor or healthcare professional involved in your medical care (e.g. in case of an emergency).

Indication for using Terflonamide

Terflonamide is used in adults and in children and adolescents (10 years of age and older) to treat relapsing remitting multiple sclerosis (MS)

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sanofi

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

Important side effects



This medication reduces the activity of the immune system (immunomodulator). In some people, 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:

- Your skin or the white of your eyes turn yellow, dark urine, nausea or vomiting and abdominal pain. In this case you may have a problem with your liver.
- Signs of an infection including, pain on passing urine, confusion, high temperature (fever), cough, swollen glands



For women of childbearing potential including girls and their parents/caregivers

- Do not start Teriflunomide when you are pregnant, or you think you may be pregnant. Teriflunomide can cause serious birth defects. Your doctor may ask you to do a pregnancy test to make sure.
- Use effective contraception while and after using Aubagio. Your doctor will provide counsellings on the potential risks to the fetus and on the need for effective contraception
- Contact your doctor if you want to change contraception method or if you want to conceive.
- If you become pregnant or think you are pregnant, stop teriflunomide and **contact your doctor immediately.**
- In case of pregnancy, your doctor may suggest treatment with certain medicines to speed up the removal of teriflunomide from your body.
- You should also discuss with your doctor if you plan to or are breastfeeding.
- For parents /caregivers or girls: please contact your doctor when the patient experiences menses for the first time in order to get counsellings about the potential risk to the fetus and the need for contraception.