

For further information, see www.medicinesauthority.gov.mt/rmm

 Treating doctor's phone number:

 Treating doctor's name:

 Centre name:

 Date Aubagio® first prescribed:

 Patient's name:

Alternatively any side effect can be reported to Sanofi Srl, at PharmacovigilanceMalta@sanofi.com
post@genzymeauthority.gov.mt

You can report side effects to the Medicines Authority using the online side effect report form Or filling in the Adverse Drug Reaction report form and sending it at Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta or via email to post@genzymeauthority.gov.mt

Call for Reporting

Patients and consumers as well as healthcare professionals can report side effects that are experienced while taking a medicine.

PATIENT CARD

This Patient Card contains important safety information you need to be aware of when receiving treatment with Aubagio®. 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).

Once-daily
AUBAGIO®
 (teriflunomide) 14mg tablets

AUBAGIO is available in 14 mg and 7 mg tablets.

SANOFI GENZYME



Important side effects

This drug may affect your liver function, your blood pressure and certain cells in your blood that are important to fight infections.

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.
- High temperature (fever), cough, chills, swollen glands, reduced or painful urine flow. In this case you may have an infection.



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

- Do not start Aubagio when you are pregnant, or you think you may be pregnant. 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 experience menses for the first time in order to get counsellings about the potential risk to the fetus and the need for contraception.