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

AUTHORISED BY THE MEDICINES AUTHORITY on 18-MAY-2020

Treating doctor's phone number: _____

Treating doctor's name: _____

Centre name: _____

Date Aubagio® first prescribed: _____

Patient's name: _____

PATIENT CARD

This Patient Card contains important safety information you need to be aware of when receiving treatment with Aubagio®. Please read thoroughly the 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) 14 mg tablets

SANOFI GENZYME

Important side effects

This drug may affect your liver function and certain cells in your blood that are important to fight infections. Therefore a blood test and blood pressure should be checked before the start of the treatment and regularly thereafter.

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 fever, shaking, chills, swollen glands, reduced or painful urine flow, or confusion. In this case you may have an infection.

For female patients only: Pregnancy

- 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 reliable contraception while using Aubagio.
- If you become pregnant or think you are pregnant, **contact your doctor immediately**.
- In case of pregnancy, your doctor may suggest treatment with certain medicines to remove Aubagio rapidly and sufficiently from your body through the accelerated elimination procedure.
- You should also discuss with your doctor if you plan to or are breastfeeding.

Call for Reporting

Patients and consumers as well as healthcare professionals can report side effects that are experienced while taking a medicine. 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 e-mail to postlicensing.medicinesauthority@gov.mt

Alternatively any side effect can be reported to Sanofi Spa, at PharmacovigilanceMalta@sanofi.com