PATIENT CARD

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

Please show this card to any doctor or healthcare professional involved in your medical care (e.g. in case of unexpected medical problems that may involve new doctors).

Aubagio® is for treating adult patients with relapsing-remitting multiple sclerosis.
This drug may affect your liver function. It may also affect blood cell counts and the immune system, and may increase the risk of infections/serious infections.

If you have any of the following symptoms, please contact your doctor immediately:

- Unexplained nausea
- Vomiting
- Stomach pain
- Dark urine
- Your skin or the whites of your eyes turn yellow.

If you are a woman of childbearing potential, you should not be pregnant prior to starting Aubagio®.
Your doctor may ask for a precautionary pregnancy test prior to issuing your Aubagio® prescription. In addition, you should use an effective contraceptive method agreed upon with your doctor.
Aubagio® does not impact efficacy of oral hormonal contraceptives.
You should inform your doctor prior to changing or stopping contraceptive measures during treatment with Aubagio®.

If there's any possibility you may be pregnant, please contact your doctor immediately.

You should also discuss with your doctor if you plan to or are breastfeeding.
Please ensure you perform and follow up blood tests and blood pressure check-ups, as arranged by your doctor. Please also make sure you have a list of all your medicines and medical conditions with you at every visit to a healthcare professional.

Patient's name:
Date Aubagio® first prescribed: _ _ / _ _ / _ _ _ _
Centre name:
Treating doctor's name:
Treating doctor's phone number:

In case of adverse event or pregnancy, your doctor may recommend an accelerated blood elimination procedure in order to speed up the elimination of Aubagio® from your body.

This procedure consists of administration of 4/8g cholestyramine three times daily or 50g activated charcoal twice daily for 11 days. The efficacy of this procedure is to be confirmed with blood tests prescribed by your doctor.
Please read the Aubagio® package leaflet for more information.
For further information or to report an Adverse Event, please contact your doctor.

Call for reporting:
Healthcare professionals should report any adverse events suspected to be associated with the use of Aubagio to Sanofi Malta Ltd., 3rd Floor, Avantech Building, St. Julian's Road, San Gwann SGN 2805. Tel: 21493022, fax 21493024

Alternatively any suspected ADRs and medication errors can be reported to the Medicines Authority. Report forms can be downloaded from HYPERLINK "http://www.medicinesauthority.gov.mt/adrportal" www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to HYPERLINK "mailto:postlicensing.medicinesauthority@gov.mt" postlicensing.medicinesauthority@gov.mt