

For further information please visit:
www.msonetoone.cz

If you experience adverse reactions or become pregnant, your doctor can recommend a procedure for accelerating the elimination of the medicine from the blood, which will speed up the elimination of Aubagio from your body.

This procedure comprises of the administration of 4 or 8 g of cholestyramine 3 times a day or 50 g of activated charcoal 2 times a day for 11 days. The efficacy of this procedure must be confirmed by blood tests, which will be determined by your doctor.

You can find more detailed information in the patient information leaflet included with Aubagio.

This medicinal product is subject to additional monitoring. This enables the quick acquisition of new safety information. You can contribute by reporting any adverse reactions that you experience. If you need further information or would like to report an adverse reaction, please contact your doctor.

This is intended solely as educational material for patients who have been prescribed the medicinal product Aubagio. This educational material contains only selected information and is not a substitute for the patient information leaflet. Before taking Aubagio, carefully read the patient information leaflet. This is not intended for distribution in waiting rooms.

Patient name:

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Date Aubagio was first prescribed:

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Name of the centre:

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Name of the attending physician:

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Telephone number of the attending physician:

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AUBAGIO

teriflunomid



"This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get."

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine. Detailed information on reporting can be found at: www.olecich.cz/hlaseni-pro-sukl/nahlasit-nezadoucucinek. The address for sending reports is Státní ústav pro kontrolu léčiv, oddělení farmakovigilance, Šrobárova 48, Praha 10, 100 41, e-mail: farmakovigilance@sukl.cz

Please always carry this card with you and show it to any doctor or health care professional who will be involved in your health care.

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PATIENT INFORMATION CARD

This “Patient Information Card” contains important safety information with which you must be familiar during treatment with Aubagio (teriflunomide). Please always carry this card with you and show it to any doctor or health care professional who will be involved in your health care (e.g. in the event of unexpected health problems due to which you see a new doctor).

Aubagio is a medicine used to treat adult patients with relapsing-remitting multiple sclerosis. This medicine may affect your liver function. It can also affect your blood count and immune system and can increase the risk of infection, including severe infections.

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

- Unexplained nausea
- Vomiting
- Stomach pain
- Dark urine
- Yellowing of the skin or whites of the eyes

It is necessary to pay attention to certain signs and symptoms that may indicate an infection, and if these occur, contact your doctor immediately.

For example, this could be the flu (fever or flu-like symptoms); infection of the sinuses or throat; urinary tract infection (infection of the urinary tract or bladder); infection of the airways (bronchitis); diarrhoea or vomiting (signs of inflammation of the stomach and intestines); cold sores (herpes of the mouth); dental infection; laryngitis; or fungal foot infection.

If you are a woman of childbearing age, you must not be pregnant before the commencement of treatment with Aubagio.

Your doctor, for safety reasons, will ask you to undergo a pregnancy test before giving you a prescription for Aubagio. Additionally, you must use contraception, the method of which will be agreed upon with your doctor. If you suspect that you are pregnant, you must immediately stop treatment with Aubagio and contact your doctor immediately.

Aubagio has no effect on the efficacy of oral hormonal contraception. Inform your doctor before making any changes in or terminating contraception during treatment with Aubagio.

Consult your doctor if you are breastfeeding or planning to breastfeed.

Please make sure you undergo all blood tests and blood pressure checks agreed upon with your doctor.

Blood tests and blood pressure checks:

Before treatment

You must have the following checked before treatment with teriflunomide:

- Blood pressure
- The ruling out of pregnancy in women
- Alanine aminotransferase (ALT/SGPT)
- A complete blood count including a white blood cell differential count and platelet count

During treatment

You must have the following checked during treatment with teriflunomide:

- Blood pressure
- Alanine aminotransferase (ALT/SGPT)
- A complete blood count according to signs and symptoms (e.g. infection) that occurred during treatment

Furthermore, do not forget to bring with you to every visit to your doctor or health care professional the list of all other medicines you are taking and your medical conditions.