









When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine. Suspected adverse reactions should also be reported to Sanofi: Tel: 0800 0902314. Émail: UK-drugsafety@sanofi.com

between 9am and 5pm. You can leave a message outside of these hours.

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday

- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

- the free Yellow Card app available from the Apple App Store or Google Play Store

- the Yellow Card website www.mhra.gov.uk/yellowcard

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

You should also read the patient information leaflet for further information.



PATIENT CARD: UK

Date territunomide first prescribed:

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Name of neurologist:

number for neurologist: Emergency phone

. I 202 тыркола : Ievorgqe Алнии то эзеч MAT-GB-2104473 (v1.0) Date of Preparation: January 2022. For further information, please contact medical information <u>uk-medicalinformation@sanofi.com</u>





Important side effects

Teriffunomide reduces the activity of the immune system (immunomodulator). In some people, teriflunomide can cause liver damage (hepatitis) and it may also reduce the production of white blood cells that fight infection (neutrophile) and platelets that are involved in blood clotting. Your liver function tests and blood pressure should be checked regularly during teriffunomide 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:

- Yellow skin or yellowing of the whites of your eyes (jaundice), unexplained nausea or vomiting, abdominal pain or darker urine than normal. These are the symptoms of a liver problem.
- 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

- Teriflunomide should not be used in pregnancy or in women of child-bearing potential if they are not using effective contraception because it can cause serious birth defects.
- Do not start teriflunomide when you are pregnant, or you think you may be pregnant. Your doctor may ask you to do a pregnancy test to make sure.
- Effective contraception should be used during and after teriflunomide treatment until the blood levels are low. Your doctor will provide counselling on the potential risks to an unborn baby and on the need for effective contraception.
- Tell your doctor if you want to change your method of contraception or plan to become pregnant after stopping treatment with Aubagio. You should also discuss with your doctor if you plan to or are breastfeeding.
- If you suspect that you are pregnant while taking Aubagio or in the two years after you
 have stopped treatment, you must contact your doctor immediately for a pregnancy test.
 If the test confirms that you are pregnant, your doctor may suggest treatment with certain
 medicines to speed up the removal of teriflunomide from your body, as this may decrease
 the risk to your baby. Your doctor will encourage enrolment in the pregnancy registry
 conducted by the National Coordination Centre: Greater Manchester Neuroscience Centre.
 Phone: 0161 206 0534. Email: neuroresearch.nurse@srft.nhs.uk.
- The parents or carers of girls should contact their daughter's doctor when they have their first period so that she can be counselled on the risk of birth defects during pregnancy and given advice on appropriate contraception.

Date of MHRA approval: December 2021.



