


Patient guide: Pregnancy

What females who could become pregnant need to know about Topiramate-Actavis (topiramate)

A circular photograph of a young woman with blonde hair tied back in a ponytail. She is wearing a light pink sweater and a red jacket. She is smiling and looking down, with her right hand raised slightly. The background is a blurred outdoor setting with trees.

Please keep this booklet. You may need it again. This booklet does not contain all the information you need to know. Ask your doctor if you have questions about treatment with topiramate.

What is topiramate?¹

Topiramate is the active ingredient in your medicine Topiramate-Actavis. It belongs to a group of medicines known as antiepileptics and can be used to treat various types of seizures and to help prevent migraines.

What are the risks of taking topiramate during pregnancy?¹

Topiramate can seriously harm an unborn child when taken by the mother during pregnancy. This booklet provides some guidance on pregnancy prevention, pregnancy planning and things to discuss with your doctor. It is important not to stop taking this medicine without speaking to your doctor. Stopping suddenly, especially when you are using topiramate in epilepsy, may increase your risk of seizures, which can also harm you and your baby.

Every pregnancy (including people not taking topiramate) starts with a small chance of having a birth defect (this is called background risk).² However, if you take topiramate during pregnancy, your child has a three-fold higher risk for birth defects such as:

- Cleft lip and cleft palate (splits in the top lip or roof of the mouth)
- Hypospadias (a malformation of the penis in boys).

In addition, if you take topiramate during pregnancy, your child may be smaller and weigh less than expected at birth. Your child may also have a 2- to 3-fold higher risk for autism spectrum disorders (ASD), intellectual disability and attention-deficit/hyperactivity disorder (ADHD) compared with children born to women with epilepsy not taking antiepileptic medication.

These risks can occur early in pregnancy, before you even know you are pregnant.

What should you remember when taking topiramate?



Need for birth control (contraception)¹

It is important to always use highly effective birth control as recommended by your doctor or gynaecologist for the whole time you are taking topiramate, and for four weeks after stopping treatment. This is to help prevent you from getting pregnant, as topiramate can harm your unborn child. Talk to your doctor about methods of birth control most appropriate for you. If you are taking oral contraceptives (“the pill”), there is a risk that they may not work as well as expected when you are taking topiramate. Therefore, an additional method of birth control such as a male or female condom or diaphragm should be used.

Before you start treatment with topiramate, your doctor will ask you to perform a pregnancy test, which should be negative before you take the medicine.

While on topiramate, tell your doctor if your menstrual bleeding (period) changes in any way.



Use of topiramate in girls¹

Topiramate may be used in people under the age of 18 to help treat various types of seizures. For a girl who has not yet experienced her first period:

- You / Your parent or caregiver should know about the risks of topiramate when used during pregnancy, as this will be important when you / the child gets older.
- You should inform your doctor as soon as you experience your first period during treatment with topiramate.
- As soon as you are sexually active, you need to use highly effective contraception. It is very important that you talk to your parents and doctor about that. Your doctor or gynaecologist will discuss appropriate methods of contraception for you.

If you already have your periods:

- In case you are sexually active, you should only be treated with topiramate if you are not pregnant and you are using highly effective contraception.



If you plan to become pregnant³

If you are considering becoming pregnant while taking topiramate, you should schedule an appointment with your doctor as soon as you can. It is important that you do not stop contraception and do not become pregnant until you have discussed your options with your doctor.

Your doctor may:

- Reassess whether you still need topiramate
- Evaluate alternative treatments
- Counsel you about the risks of topiramate during pregnancy
- Refer you to another specialist.



If you become pregnant while taking topiramate¹

Talk promptly to your doctor about your options and what you need to know. If you are taking topiramate for epilepsy, notify your doctor immediately and do not stop taking the medicine until you have seen your doctor. Stopping treatment suddenly may worsen your illness, which may put you or your unborn child at risk.

If you are taking topiramate to prevent migraine, stop taking the medicine straight away and contact your doctor to evaluate if you need alternative treatment.

Your doctor will:³

- Reassess your treatment, and evaluate alternative treatment options
- Assess the risks to you and your unborn baby
- Refer you to a specialist for prenatal monitoring to check how your child is developing, if treatment with topiramate is continued
- Advise you on any changes to your dosage and the need for folic acid supplementation
- Support you in deciding whether to continue or change treatment.

Consult your doctor regularly, at least each year. During this visit you may read and sign a Risk Awareness Form together with your doctor to ensure you know and understand the risks related to using topiramate during pregnancy and the need to use highly effective contraception. Your doctor may reassess your need for topiramate and consider alternative treatment options.

References:

1. Topiramate-Actavis Consumer Medicine Information. Available at: <https://www.medsafe.govt.nz/Consumers/CMI/t/topiramateactavis.pdf> (accessed July 2025).
2. Mother to Baby Fact Sheet. Topiramate. Available at: https://www.ncbi.nlm.nih.gov/books/NBK582991/pdf/Bookshelf_NBK582991.pdf (accessed July 2025).
3. Topiramate Actavis Data Sheet. Available at: <https://www.medsafe.govt.nz/profs/Datasheet/t/topiramateactavistab.pdf> (accessed July 2025).