

Topiramate▼ Pregnancy Prevention Programme

Patient Guide

Epilepsy

This medicine will be referred to as topiramate throughout this guide and covers the brands Topamax, Topamax Sprinkle, Topiramate Accord, Topiramate Milpharm, Topiramate Cadila, Topiramate Crescent, Topiramate Glenmark, Topiramate Morningside, Topiramate Renata, Topiramate Rosemont, Topiramate Torrent, Topiramate Mylan, Topiramate Zydus Pharmaceuticals UK

▼ *This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get. You can talk to your doctor, pharmacist or nurse or you can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.*

Patient Guide: What patients who are able to get pregnant need to know about topiramate

This guide is for you (or your parent/caregiver/responsible person) if you are a patient (of any age) who can get pregnant and are taking any medicine containing the active ingredient topiramate. Topiramate is available as various brand names which are listed at the top of this guide.

It contains important information about the risks of taking topiramate during pregnancy.

You might find it helpful to talk about this guide with your partner, friends and family.

READ THIS GUIDE ALONG WITH THE PATIENT INFORMATION LEAFLET WHICH IS INCLUDED IN YOUR BOX OF MEDICATION.

Keep this guide safe. You may need to read it again.

Do not stop taking topiramate unless your specialist tells you to. Suddenly stopping topiramate can cause seizures to start again or happen more often and last longer than before.

Ask your specialist, GP or other healthcare professional who is involved in the management of your condition if you have any questions.

More information can also be found online at www.medicines.org.uk by entering "topiramate" in the search box and then clicking on "Risk Materials" next to any of the medicines that appear.

The information in this Guide has been approved by the UK medicines regulator, the MHRA.

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Important Information to Remember

- Topiramate is an effective medicine for epilepsy.
- If you take topiramate when pregnant, it can **seriously harm the baby**.
- **Never stop taking topiramate before discussing with your specialist first.** Suddenly stopping topiramate can cause seizures to start again or happen more often and last longer than before.
- **If you are able to get pregnant, use effective contraception (birth control) at all times during treatment with topiramate.** This is to reduce the risk of unplanned pregnancy. Some methods of birth control are more effective than others. Your General Practitioner (GP), specialist, sexual health and contraception clinic or contraception service in community pharmacy will discuss which method of birth control is best for you.
- **Schedule an urgent appointment with your GP if you think you are pregnant.** Your GP will refer you immediately to your specialist.
- Consult your GP to be urgently referred to your specialist if you are thinking about having a baby. Do not stop using contraception (birth control) until you and your specialist agree on what is the best treatment option for you.
- You should see your specialist regularly – at least once a year. Your specialist should discuss and complete the Annual Risk Awareness Form with you. This is to make sure you are aware of the risks of use of topiramate use during pregnancy and the need to avoid becoming pregnant whilst taking topiramate.

Contraception for patients who are able to become pregnant

Why do I need to use contraception (birth control)?

This is to stop you getting pregnant on topiramate.

Use contraception (birth control) at all times while you are taking topiramate.

Use contraception (birth control) even if you are not currently sexually active. This is unless you and your doctor agree there are good reasons why you are not at risk of pregnancy.

If your specialist recommends that you change or stop topiramate, continue to use contraception (birth control) for four weeks after the last dose of topiramate. This is to make sure that you do not become pregnant while there is a risk that some topiramate may remain in your body.

What type of contraception (birth control) should I use?

Some methods of birth control are more effective than others. The most effective contraceptive methods include intrauterine devices (IUDs) with copper or hormones.

Topiramate can affect how well some hormonal contraceptive (birth control) methods work. Using an additional barrier method, such as condom or vaginal ring pessary/diaphragm may be necessary.

Discuss with your GP, specialist, professional at sexual health and contraception clinic, or contraception service in your community pharmacy about which method of contraception (birth control) is best for you and will be suitable alongside topiramate.

What are the risks of taking topiramate during pregnancy?

If you take topiramate when you are pregnant it can seriously harm your baby.

The risk may be higher with higher doses of topiramate but all doses carry a risk. The risk may also be higher when topiramate is used in combination with other medicines to treat epilepsy.

Effects on growth and development in the womb

Your baby may be smaller and weigh less than expected at birth.

Most small babies are usually healthy but your baby may need extra tests and monitoring during pregnancy to check their wellbeing.

For women who take topiramate while pregnant, around 18 babies in every 100 will be smaller and weigh less than expected at birth.

This compares with women in the general population, around 5 babies in every 100 will be smaller and weigh less than expected at birth.

Birth Defects

Taking topiramate during pregnancy can cause birth defects.

For women who take topiramate while pregnant, around 4 to 9 babies in every 100 will have birth defects.

This compares with women in the general population, around 1 to 3 babies in every 100 will have a birth defect.

What type of birth defects can happen?

Babies can be born with a cleft lip, a cleft palate or both. A cleft is a gap or split in the upper lip and/or roof of the mouth (palate). It is present from birth.

Newborn baby boys may also have a malformation of the penis (hypospadias). This is where the opening of the urinary tract (the urethra) is lower than it should be.

Mental development and learning problems

Children of mothers who take topiramate in pregnancy may be at an increased risk of having:

- autism or autism spectrum disorders
- attention deficit hyperactivity disorder (ADHD)
- intellectual disabilities

Children of mothers who took topiramate during pregnancy have a 2 to 3 times higher risk of these problems. This is compared with children of women who do not have epilepsy and did not take an epilepsy medicine during pregnancy.

What does this mean for me?

I am starting treatment with topiramate

Your specialist will discuss the benefits and risks of topiramate with you. This will explain why they feel topiramate is the right medicine for you and tell you about the known risks.

- **Patients who have not yet experienced their first period:**
 - o You/your child should know about the risks of topiramate when used during pregnancy.
- **As soon as the patient experiences their first period whilst taking topiramate:**
 - o You should contact your/their specialist
 - o The specialist will decide with you/your child whether topiramate remains the right medicine. This decision will consider the risks and also whether their condition is not adequately treated by other medicines. They may try to switch you/your child to another medicine with a lower risk to a baby.
 - o The specialist may ask you/your child to perform a pregnancy test, because you/they must not take topiramate if you/they are pregnant.
- **Patients who have started having periods:**
 - o You should be treated with topiramate only if your specialist has consulted with you about the risks and benefits. This will include whether your condition is not adequately treated by other medicines and that the benefits of topiramate outweigh the risks.
 - o If you are able to get pregnant, your specialist will discuss the need to use effective contraception (birth control) with you/your child.
 - o Your specialist may ask you to perform a pregnancy test.

Your specialist will review your/your child's treatment regularly, and at least once a year.

At the initial visit and at each annual review, your specialist will discuss the risks with you/your child. You will also complete an Annual Risk Awareness Form. This is to make sure you/your child are aware of all the risks of use of topiramate during pregnancy and the need to avoid becoming pregnant whilst taking topiramate.

If there is a compelling reason that you/your child are not at risk of becoming pregnant then you/your child may not need to use contraception (birth control). This joint decision should be documented in your Annual Risk Awareness Form.

During these visits your specialist will decide with you/your child whether the benefits of topiramate outweigh the risks for you/your child. They may discuss switching you/your child to another medicine.

I am taking topiramate and not planning to have a baby

Your specialist will review your treatment with you regularly (at least once a year).

During these visits, your specialist will discuss and complete an Annual Risk Awareness Form with you. You will be asked to sign this form. This is to make sure you are aware of all the risks related to the use of topiramate during pregnancy and the need to avoid becoming pregnant whilst taking topiramate.

During the annual review your specialist will decide with you whether the benefits of topiramate outweigh the risks for you. They may discuss switching you to another medicine.

If you are taking topiramate and able to have a baby, **always use effective contraception (birth control) during your treatment.**

Topiramate can affect how well some hormonal contraceptive (birth control) methods work. Using an additional barrier method, such as condom or vaginal ring pessary/diaphragm may be necessary.

If you and your specialist agree that there are compelling reasons that you are not at risk of becoming pregnant then you may not need to use contraception (birth control). This joint decision should be documented in your Annual Risk Awareness form.

Talk to your GP, epilepsy team, professional at the sexual health and contraception clinic, or contraception service in community pharmacy if you need advice on contraception (birth control).

Tell your GP or specialist immediately, if you think you are pregnant. Your GP should refer you immediately to your specialist.

Do not stop taking topiramate until you have discussed this with your specialist even if you have become pregnant. Suddenly stopping topiramate can be dangerous as it may cause you to have more seizures or seizures that are more severe.

I am taking topiramate and planning to have a baby

It is important that you do not become pregnant until you have discussed your options with your specialist.

Your specialist will:

- Discuss with you the risks related to the use of topiramate during pregnancy.
- Reassess your treatment as they may need to change or stop your medicine.

If you are taking topiramate for epilepsy, any change of medicine should be a long time (i.e. several months) before you become pregnant.

Topiramate can harm babies even in early pregnancy. It is important that you do not delay seeing your specialist if you think you may be pregnant.

If you are planning a baby, first schedule an appointment with your GP to be referred to your specialist but:

- **Keep taking topiramate**
- **Keep using contraception (birth control) until you have talked with your specialist.**

If your specialist recommends that you change or stop topiramate, continue to use contraception (birth control) for four weeks after the last dose of topiramate. This is to make sure that you do not become pregnant while there is a risk that some topiramate may remain in your body.

I am taking topiramate and I have become pregnant

Do not stop taking topiramate unless your specialist tells you to.

Suddenly stopping can be dangerous and may cause seizures to start again or happen more often or last longer than before.

Immediately schedule an appointment with your specialist, or GP to be urgently referred to your specialist. Your specialist will assess your condition and discuss your options with you.

Your specialist may advise that you need to switch to another treatment. They will explain how to make the change from topiramate to another treatment.

If you take topiramate during pregnancy, your child will have a higher risk of:

- Being born smaller and weighing less than expected
- Birth defects
- Mental development and learning problems

These may seriously affect your child's life.

Please also refer to section 3: "What are the risks of taking topiramate during pregnancy?"

In some circumstances, it may not be possible to switch to another treatment. Please refer to your specialist for additional information.

You will be monitored very closely:

- This is to make sure your condition is controlled
- It is also to check how your baby is developing

Further sources of information

You may find the following organisations helpful if you are looking for information about epilepsy:

Epilepsy Action www.epilepsy.org.uk 0808 800 5050

Epilepsy Society www.epilepsysociety.org.uk 01494 601 400

Young Epilepsy www.youngpilepsy.org.uk

More information can also be found online at www.medicines.org.uk by entering "topiramate" in the search box and then clicking on "Risk Materials" next to any of the medicines that appear. You can also search online for "MHRA topiramate".

