

# Topiramate▼ Pregnancy Prevention Programme

## Patient Guide

### Prophylaxis of migraine

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](http://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 patients 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.

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

You may find the following organisation helpful if you are looking for information about migraine:

Migraine Trust [www.migrainetrust.org](http://www.migrainetrust.org) 0808 802 0066

More information can also be found online at [www.medicines.org.uk](http://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.**

## **Contents**

<b>1. Important information to remember</b>	<b>Page 4</b>
<b>2. Contraception for patients who are able to become pregnant</b>	<b>Page 5</b>
<b>3. What are the risks of taking topiramate during pregnancy?</b>	<b>Page 6</b>
o Effects on growth and development in the womb	Page 6
o Birth defects	Page 6
o Mental development and learning problems	Page 7
<b>4. What does this mean for me?</b>	<b>Page 8</b>
o I am starting treatment with topiramate	Page 8
o I am taking topiramate and not planning to have a baby	Page 9
o I am taking topiramate and planning to have a baby	Page 10
o I am taking topiramate and I have become pregnant	Page 10

## Important information to remember.

- Topiramate is an effective medicine for the prevention of migraine headaches.
- If you take topiramate when pregnant, it can **seriously harm the baby**.
- **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 an unplanned pregnancy. Some methods of birth control are more effective than others. Your General Practitioner (GP) will discuss with you which method of birth control is best for you.
- **If you think you are pregnant, stop taking topiramate straight away. Contact your GP as soon as possible to discuss your options.**
- Consult your GP if you are thinking about having a baby. Do not stop using contraception (birth control) until you have spoken to your GP.
- You should see your GP regularly – at least once a year. Your GP will 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 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 while taking 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 treatment with topiramate is stopped, 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, 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.

### **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, where 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, where 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

Studies suggest that children of mothers with epilepsy 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.

Although these studies were in children of mothers with epilepsy, the same risks are also considered to apply when topiramate is used for other conditions, including prevention of migraine.

## What does this mean for me?

### I am starting treatment with topiramate

**Your healthcare professional will discuss the benefits and risks of topiramate with you. They will explain why they feel topiramate is the right medicine for you and tell you about the known risks.**

This will include whether your condition is not adequately treated by other medicines and that the benefits of topiramate outweigh the risks.

If you can get pregnant, **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

Your healthcare professional may ask you to perform a pregnancy test to exclude pregnancy prior to starting topiramate.

Your healthcare professional will discuss and complete an Annual Risk Awareness Form with you. This is to make sure you are aware of all the risks of use of topiramate during pregnancy and the need to avoid becoming pregnant whilst taking topiramate.

If you and your healthcare professional 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.

## I am taking topiramate and not planning to have a baby

Your healthcare professional will review your treatment regularly, and at least once a year.

During these visits, your healthcare professional 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 healthcare professional will decide with you whether the benefits of topiramate outweigh the risks for you.

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 healthcare professional 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, 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 immediately, if you think you are pregnant.

## 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 GP.

Your GP will:

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

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

### **If you are planning a baby, schedule an appointment with your GP but:**

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

If topiramate is stopped, 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

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.

### **Stop taking topiramate straight away.**

**Contact your GP as soon as possible.** Your GP will assess your condition and discuss your options with you.

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



