

Topamax[▼] (topiramate) Pregnancy Prevention Programme

Patient Guide on Contraception and Pregnancy

Topiramate: Contraception and Pregnancy – what you should know

This guide is for you (or your parent/legal guardian), if you are a girl or a woman who can become pregnant and you are taking any medicine containing topiramate.

It contains key information about the risks of topiramate use during pregnancy. Ask your doctor, nurse, or pharmacist if you have any questions.

Read this Guide along with the leaflet inside the medicine box.



Latest approved information (Patient Card, Patient Guide, Patient Information Leaflet, Annual Risk Awareness Form) on this medicine is available by scanning the following QR code with a smartphone. The same information is also available on the following website (URL): www.topamaxandme.ie.

This Guide has been approved by the Health Products Regulatory Authority

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1. Purpose of this guide

This guide is for you (or your parent/legal guardian) if you are a girl or woman who can become pregnant and you are taking any medicine containing topiramate (Topamax). It is part of the **topiramate Pregnancy Prevention Programme**, which aims to minimise the risks that could occur through the use of topiramate during pregnancy.

- It contains key information about the risks of taking topiramate during pregnancy and the measures you need to take while being treated with topiramate.
- It is important to read this if your doctor has recommended topiramate as the best treatment for you.
- Read this booklet along with the leaflet inside the medicine box.
- It is important that you read the leaflet inside the medicine box, even if you have been taking topiramate for a while.
- This is because it contains the most up to date information on your medicine.
- Ask your doctor, midwife, nurse or pharmacist if you have any questions.

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

Epilepsy Ireland

www.epilepsy.ie
01 455 7500

Migraine Association of Ireland

www.migraine.ie
Phone: 01 894 1280/1281
Information Line: 01 906 1012 (all Ireland)

2. What are the risks to your baby from taking topiramate during pregnancy?

Topiramate can seriously harm an unborn child when taken during pregnancy. However, if you are taking topiramate for epilepsy you should never stop taking it unless your doctor tells you so because your epilepsy may become worse, which may also put you and your unborn child at risk.

Birth defects



If you take **topiramate** during pregnancy, your child has a **3-fold higher risk for birth defects**, particularly

- Cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth).
- Newborn boys may also have a malformation of the penis (hypospadias).

These defects can develop early in pregnancy, even before you know you are pregnant.



Reduced growth

If you take topiramate during pregnancy, your **child may be smaller and weigh less than expected** at birth. In one study, 18 % of children of mothers taking topiramate during pregnancy were smaller and weighed less than expected at birth, while 5 % of children born to women without epilepsy and not taking antiepileptic medication were smaller and weighed less than expected at birth.



Development and learning problems

If you take topiramate during pregnancy, your child may have a **2 to 3 fold higher risk for autism spectrum disorders, intellectual disabilities, or attention deficit hyperactivity disorder (ADHD)** compared with children born to women with epilepsy not taking antiepileptic medication.

3. Key information to remember

- Topamax (topiramate) is an effective medicine for epilepsy and migraine prevention.
- Topiramate can **seriously harm an unborn child** when taken during pregnancy.
- If you are able to become pregnant, talk to your doctor about other possible treatments.
- If you are able to become pregnant and need to use topiramate **always use highly effective contraception (birth control)** that has been recommended by your doctor at all times during your treatment and for at least four weeks after stopping treatment.
- Consult your doctor if you are thinking about having a baby and do not stop using contraception (birth control) until you have done so.
- Make an urgent appointment with your doctor if you think you are pregnant.
- If you are taking topiramate for epilepsy, do not stop taking it before discussing with your doctor first because your condition may become worse.
- Remember to visit your doctor regularly – at least once a year. When you start your treatment and during your annual visits, you and your doctor will discuss and sign an Annual Risk Awareness Form. This is to ensure you understand the risks related to the use of topiramate during pregnancy and the need to avoid becoming pregnant while taking topiramate.

4. Contraception (birth control)



Talk to your doctor about the method of birth control (contraception) that is most appropriate for you.

One highly effective contraception (such as an intrauterine device) or two complementary contraceptives such as birth control pill together with a barrier method of birth control (such as a condom or pessary/diaphragm) is recommended.

If you are taking hormonal contraceptives, there is the risk for reduced effectiveness of hormonal contraceptives due to topiramate. Therefore, an additional barrier contraceptive method such as a condom or pessary/diaphragm should be used.

Tell your doctor if your menstrual bleeding changes while you are taking hormonal contraceptives and topiramate. Irregular bleeding may occur. In this case, continue taking the hormonal contraceptives and inform your doctor.

5. 'I am an adult - what does this mean for me?'

'I AM TAKING TOPIRAMATE AND NOT PLANNING TO HAVE A BABY'

Topiramate can **harm an unborn child**.

If you are able to become pregnant, talk to your doctor about **other possible treatments**.

Your doctor will ask you to **perform a pregnancy test before starting** topiramate, to make sure you are not pregnant.

It is important that you always use **highly effective contraception (birth control) at all times** during treatment with topiramate. This is to make sure you do not become pregnant (see section 4 **Contraception (birth control)**).

Talk to your GP, nurse or professional at the family planning clinic if you need advice on the method of contraception.

You will need to review your treatment with your doctor regularly (at least each year). When you start treatment and during each annual review, you and your doctor will read and sign the Annual Risk Awareness Form. This is to make sure you are well aware of and have understood the risks related to the use of topiramate during pregnancy and the need to avoid becoming pregnant while taking topiramate.

'I AM TAKING TOPIRAMATE AND PLANNING TO HAVE A BABY'



Schedule an appointment with your doctor.

It is important that you **do not stop using highly effective contraception (birth control)** and **do not become pregnant** until you have discussed your options with your doctor



I am taking topiramate for Epilepsy

- **Do not stop taking topiramate** until you have discussed this with your doctor because **your epilepsy may become worse**.
- Your doctor will **reassess your treatment and evaluate alternative treatment options**. They may need to refer you to a specialist for this.
- The doctor will **counsel you about the risks of topiramate during pregnancy** using the Annual Risk Awareness Form.



I am taking topiramate for Migraine Prevention

- You will need to **stop topiramate treatment before you become pregnant**.
- Your doctor will **reassess your treatment** and evaluate alternative treatment options. Your doctor will **counsel you about the risks of topiramate during pregnancy** using the Annual Risk Awareness Form.

'I AM TAKING TOPIRAMATE AND I THINK I MAY BE OR I AM PREGNANT'



I am taking topiramate for Epilepsy

- **Talk urgently to your doctor** about your treatment options and what you need to know.
- **Do not stop taking topiramate** until you have discussed this with your doctor, **as this may worsen your epilepsy**. Worsening of your epilepsy may put you or your unborn child at risk.
- Your doctor may need to **arrange for specialist review**. The specialist will **reassess your treatment** and evaluate alternative treatment options. The specialist will **counsel you about the risks of topiramate during pregnancy** using the Annual Risk Awareness Form.
- The specialist will explain if you need to **switch to another treatment** and how.
- **Your doctor will refer you to a specialist (obstetrician) for close monitoring** to check how your baby is developing.



I am taking topiramate for Migraine Prevention

- Schedule **an urgent appointment** with your doctor.
- **Stop taking topiramate straightaway**.
- The doctor will counsel you about the **risks of topiramate during pregnancy** using the Annual Risk Awareness Form.
- Your doctor will evaluate if you need alternative treatment.
- Your doctor will **refer you to a specialist (obstetrician) for close monitoring** to check how your baby is developing.

6. 'I am a parent/legal guardian of a girl taking topiramate, what does this mean for my child?'

Never stop taking topiramate without talking to your doctor.

The doctor will explain why topiramate is the right medicine to treat your child's epilepsy. Topiramate can seriously harm an unborn child, if taken during pregnancy.

- It is important that you (and your child when she is old enough) understand the risks associated with topiramate when used during pregnancy.
- When your child's periods start, it is important to contact your child's doctor. They may arrange review of your child by a specialist.
- During this visit the doctor will:
 - reassess treatment with topiramate and evaluate alternative treatment options.
 - explain the risks to an unborn baby from taking topiramate during pregnancy.
 - discuss the need for birth control when relevant, to prevent pregnancy while taking topiramate.
 - discuss the need for pregnancy testing when relevant because topiramate should not be taken during pregnancy.
 - complete an Annual Risk Awareness Form with you (and your child if she is old enough).
 - Your doctor will arrange to see your child regularly (at least once a year) to review her treatment. They will complete the Annual Risk Awareness Form with you. This is to make sure that, when she is old enough, she is well aware of and understands all the risks related to the use of topiramate during pregnancy and the need to avoid becoming pregnant while taking topiramate.

Annual Review

- Once your child has had her first period, she will need to review her treatment with her specialist at least once a year.
- During this visit, you/your child (when she is old enough) will be asked to complete an Annual Risk Awareness Form to ensure you know and understand the risks to a baby from taking topiramate during pregnancy and the need to avoid becoming pregnant while taking topiramate.

If you have any questions, please ask your doctor.

Notes

A series of 20 horizontal dotted lines for writing notes.

Electronic copies of this Guide and other materials related to the topiramate pregnancy prevention programme can also be found online at www.hpra.ie. Enter «Topamax» or «topiramate» in the search box and then click on «EdM» next to any of the medicines that appear.

Electronic copies of this Guide and other materials related to the topiramate Pregnancy Prevention Programme can also be found online at www.medicines.ie.

▼ **This medicinal product is subject to additional monitoring. If you get any side effects, talk to your doctor, pharmacist or nurse. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. This includes any side effects not listed in the package leaflet. You can also report side effects via: HPRA Pharmacovigilance, Website: www.hpra.ie.**

Adverse events should also be reported to Janssen Sciences Ireland UC on 0044(0)1494 567447 or email dsafety@its.jnj.com. By reporting side effects you can help provide more information on the safety of this medicine.