

Important Safety Information on Topiramate (TOPAMAX)
PATIENT GUIDE

What females who are able to become pregnant need to know about topiramate (TOPAMAX)

Please keep this booklet. You may need to read it again.

This risk minimization document has been reviewed and approved by the Saudi Food and Drug Authority (SFDA), Oct 2024, Version 1

What are the risks of 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.
- If you take **topiramate** during pregnancy, your child has a threefold **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.

- 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.

What are the risks of taking topiramate during pregnancy? (Cont'd)

- 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.

What you should remember when taking topiramate

Need for contraception

- **Always use highly effective contraception** recommended by your doctor or gynaecologist for the whole time you are taking topiramate and for four weeks after stopping treatment.
- This is to prevent you getting pregnant on topiramate since it can harm your unborn child.
- Talk to your doctor about the method of birth control (contraception) that is most appropriate for you.
- 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.

Use in girls {for epilepsy only}

For a girl who has **not yet experienced her first periods**:

- You/the 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.
- Inform the doctor as soon as the **girl experiences her first periods** during topiramate treatment.
- 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 your doctor about that. Your doctor or gynaecologist will counsel about which method of contraception is best for you.

What you should remember when taking topiramate (Cont'd)

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 wish to become pregnant while taking topiramate

- Schedule an appointment with your doctor. It is important that you do not stop using contraception (birth control) and do not become pregnant until you have discussed your options with your doctor.
- Your doctor will reassess your treatment and evaluate alternative treatment options. The doctor will counsel you about the risks of topiramate during pregnancy. He/she may also refer you to another specialist.

If you have become pregnant or think you may be pregnant while taking topiramate

- If you are taking topiramate for **epilepsy**, do not stop taking this medicine until you have discussed this with your doctor, as this may worsen your illness. Worsening of your epilepsy 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 reassess your treatment and evaluate alternative treatment options. The doctor will counsel you about the risks of topiramate during pregnancy.
- **Talk promptly to your doctor** about your options and what you need to know.
- Your doctor will explain when and how to switch to another treatment, if needed.
- If treatment with topiramate is continued, make sure you are referred to a specialist for prenatal monitoring to check how your child is developing.

ADVERSE EVENTS REPORTING GUIDANCE

SFDA (National Pharmacovigilance center)

Email: npc.drug@sfda.gov.sa

Telephone: 19999

Online: http://ade.sfda.gov.sa

For full prescribing information, please refer to the datasheet or contact Johnson & Johnson Trading Limited (Riyadh)

Address: Prince Muhammed Bin Abdulaziz Rd, Tower B, Level 30, Olaya towers. Postal address: P O Box 65305 Riyadh 11556, Saudi Arabia, Office Tel 00966-11-4339133

To report Adverse Events/Product Complaint or any Medical Information Inquiries, please contact us at:

Email: GCC-PV2@its.jnj.com, Hotline: 00966540015811

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Consult your doctor regularly – at least each year. During this visit you will read <and sign> a Risk Awareness Form together with your doctor to ensure you know and understand the risks related to topiramate use during pregnancy and the need to use highly effective contraception. This visit is also to check the need for your topiramate treatment and to consider alternative treatment options.

October 2024