

You should not stop your treatment without discussing this with your doctor. Suddenly stopping may lead to breakthrough seizures which may harm you and your unborn baby. It is important that your epilepsy remains well controlled.

As with other anti-epileptic medicines, there is a risk of harm to the unborn child if Topamax is used during pregnancy. Make sure you are very clear about the risks and the benefits of using Topamax for epilepsy during pregnancy.

- If you take Topamax during pregnancy, your baby has a 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.
- Studies with women treated with Topamax for epilepsy have shown that on average 4-5 babies in every 100 will have serious physical birth abnormalities. This compares to 2 to 3 babies in every 100 born to women who do not have epilepsy.
- The higher the dose of Topamax, the higher the risk of physical birth abnormalities but all doses carry a risk. It is important that where possible you are prescribed the lowest dose to control your epilepsy.
- Taking more than one epilepsy medicine at the same time may also increase the risk of physical birth abnormalities. This means that where possible, your doctor should consider using one epilepsy medicine to control your epilepsy.
- If you take Topamax during pregnancy, your baby may be smaller than expected at birth. Talk to your doctor if you have questions about this risk during pregnancy.
- There may be other medicines to treat your condition that have a lower risk of birth defects.

Breast-feeding

The active substance in Topamax (topiramate) passes into human milk. Effects have been seen in breastfed babies of treated mothers, including diarrhea, feeling sleepy, feeling irritable, and poor weight gain. Therefore, your doctor will discuss with you whether you abstain from breast-feeding or whether to abstain from treatment with Topamax. Your doctor will take into account the importance of the medicine to the mother and the risk for the baby.

Mothers who breast-feed while taking Topamax must tell the doctor as soon as possible if the baby experiences anything unusual.

Driving and using machines

Dizziness, tiredness, and vision problems may occur during treatment with Topamax. Do not drive or use any tools or machines without talking to your doctor first.

Topamax contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Other ingredients

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 How to take Topamax

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Your doctor will usually start you on a low dose of Topamax and slowly increase your dose until the best dose is found for you.
- Topamax tablets are to be swallowed whole. Avoid chewing the tablets as they may leave a bitter taste.
- Topamax can be taken before, during, or after a meal. Drink plenty of fluids during the day to prevent kidney stones while taking Topamax.

If you take more Topamax than you should

- See a doctor right away. Take the medicine pack with you.
- You may feel sleepy, tired, or less alert; lack coordination; have difficulty speaking or concentrating; have double or blurred vision; feel dizzy due to low blood pressure; feel depressed or agitated; or have abdominal pain, or seizures (fits).

Overdose can happen if you are taking other medicines together with Topamax.

If you forget to take Topamax

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Topamax

Do not stop taking this medicine unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop this medication, your dose may be decreased gradually over a few days.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor, or seek medical attention immediately if you have the following side effects:

Very common (may affect more than 1 in 10 people)

- Depression (new or worse)

Common (may affect up to 1 in 10 people)

- Seizures (fits)
- Anxiety, irritability, changes in mood, confusion, disorientation
- Problems with concentration, slowness of thinking, loss of memory, problems with memory (new onset, sudden change or increased severity)

- Kidney stone, frequent or painful urination

Uncommon (may affect up to 1 in 100 people)

- Increased acid level in the blood (may cause troubled breathing including shortness of breath, loss of appetite, nausea, vomiting, excessive tiredness, and fast or uneven heart beats)
- Decreased or loss of sweating (particularly in young children who are exposed to high temperatures)
- Having thoughts of serious self-harm, trying to cause serious self-harm
- Loss of part of the field of vision

Rare (may affect up to 1 in 1,000 people)

- Glaucoma – blockage of fluid in eye causing increased pressure in the eye, pain, or decreased vision
- Difficulty thinking, remembering information, or solving problems, being less alert or aware, feeling very sleepy with low energy – these symptoms may be a sign of a high level of ammonia in the blood (hyperammonemia), which can lead to a change in brain function (hyperammonemic encephalopathy).
- Serious skin reactions, such as Stevens-Johnson syndrome and toxic epidermal necrolysis - these may appear as rashes with or without blisters. Skin irritation, sores or swelling in the mouth, throat, nose, eyes and around the genitals. The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life-threatening consequences.

Not known (frequency cannot be estimated from the available data)

- Inflammation of the eye (uveitis) with symptoms such as eye redness, pain, sensitivity to light, runny eyes, seeing small dots or getting blurred vision

Other side effects include the following, if they get serious, please tell your doctor or pharmacist:

Very common (may affect more than 1 in 10 people)

- Stuffy, runny nose or sore throat
- Tingling, pain and/or numbness of various body parts
- Sleepiness, tiredness
- Dizziness
- Nausea, diarrhoea
- Weight loss

Common (may affect up to 1 in 10 people)

- Anaemia (low blood count)

- Allergic reaction (such as skin rash, redness, itching, facial swelling, hives)
- Loss of appetite, decreased appetite
- Aggression, agitation, anger, abnormal behaviour
- Difficulty falling or staying asleep
- Problems with speech or speech disorder, slurred speech
- Clumsiness or lack of coordination, feeling of unsteadiness when walking
- Decreased ability to complete routine tasks
- Decreased, loss of, or no sense of taste
- Involuntary trembling or shaking; rapid, uncontrollable movements of the eyes
- Visual disturbance, such as double vision, blurred vision, decreased vision, difficulty focusing
- Sensation of spinning (vertigo), ringing in the ears, ear pain
- Shortness of breath
- Cough
- Nose bleeds
- Fever, not feeling well, weakness
- Vomiting, constipation, abdominal pain or discomfort, indigestion, stomach or intestinal infection
- Dry mouth
- Hair loss
- Itching
- Joint pain or swelling, muscle spasms or twitching, muscle aches or weakness, chest pain
- Weight gain

Uncommon (may affect up to 1 in 100 people)

- Decrease in platelets (blood cells that help stop bleeding), decrease in white blood cells that help to protect you against infection, decrease in potassium level in the blood
- Increase in liver enzymes, increase in eosinophils (a type of white blood cell) in the blood
- Swollen glands in the neck, armpit, or groin
- Increased appetite
- Elevated mood
- Hearing, seeing, or feeling things that are not there, severe mental disorder (psychosis)
- Showing and/or feeling no emotion, unusual suspiciousness, panic attack
- Problems with reading, speech disorder, problems with handwriting
- Restlessness, hyperactivity
- Slowed thinking, decreased wakefulness or alertness
- Reduced or slow body movements, involuntary abnormal or repetitive muscle movements
- Fainting
- Abnormal sense of touch; impaired sense of touch
- Impaired, distorted, or no sense of smell
- Unusual feeling or sensation that may precede a migraine or a certain type of seizure
- Dry eye, sensitivity of the eyes to light, eyelid twitching, watery eyes
- Decreased or loss of hearing, loss of hearing in one ear
- Slow or irregular heartbeat, feeling your heart beating in your chest
- Low blood pressure, low blood pressure upon standing (consequently, some people taking Topamax may feel faint, dizzy, or may pass out when they stand up or sit up suddenly)
- Flushing, feeling warm
- Pancreatitis (inflammation of the pancreas)
- Excessive passing of gas or wind, heartburn, abdominal fullness or bloating
- Bleeding gums, increased saliva, drooling, breath odour
- Excessive intake of fluids, thirst
- Skin discolouration

- Muscle stiffness, pain in side
- Blood in urine, incontinence (lack of control) of urine, urgent desire to urinate, flank or kidney pain
- Difficulty getting or keeping an erection, sexual dysfunction
- Flu-like symptoms
- Cold fingers and toes
- Feeling drunk
- Learning disability

Rare (may affect up to 1 in 1,000 people)

- Abnormally elevated mood
- Loss of consciousness
- Blindness in one eye, temporary blindness, night blindness
- Lazy eye
- Swelling in and around the eyes
- Numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to the cold
- Inflammation of the liver, liver failure
- Abnormal skin odour
- Discomfort in your arms or legs
- Kidney disorder

Not known (frequency cannot be estimated from the available data)

- Maculopathy is a disease of the macula, the small spot in the retina where vision is keenest. You should call your doctor if you notice a change or decrease in your vision.

Children

The side effects in children are generally similar to those seen in adults, but the following side effects may be more common in children than adults:

- Problems with concentration
- Increased acid level in the blood
- Having thoughts of serious self-harm
- Tiredness
- Decreased or increased appetite
- Aggression, abnormal behaviour
- Difficulty falling or staying asleep
- Feeling of unsteadiness when walking
- Not feeling well
- Decrease in potassium level in the blood
- Showing and/or feeling no emotion
- Watery eyes
- Slow or irregular heartbeat

Other side effects that may occur in children are:

Common (may affect up to 1 in 10 people)

- Sensation of spinning (vertigo)
- Vomiting
- Fever

Uncommon (may affect up to 1 in 100 people)

- Increase in eosinophils (a type of white blood cell) in the blood
- Hyperactivity
- Feeling warm
- Learning disability

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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**. By reporting side effects, you can help provide more information on the safety of this medicine.