Topamax® 100 mg film-coated tablets

topiramate

IE6003002P99-A2.0

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Topamax is and what it is used for
2. What you need to know before you take Topamax
3. How to take Topamax
4. Possible side effects
5. How to store Topamax
6. Contents of the pack and other information

1. WHAT TOPAMAX IS AND WHAT IT IS USED FOR

Topamax belongs to a group of medicines called “anti-epileptic medicines”.
It is used:
- alone to treat seizures in adults and children over age 6
- with other medicines to treat seizures in adults and children aged 2 years and above
- to prevent migraine headaches in adults

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TOPAMAX

Do not take Topamax

- if you are allergic to topiramate or any of the other ingredients of this medicine (listed in section 6).

Migraine prevention
- You must not use Topamax if you are pregnant.
- If you are a woman who is able to become pregnant, you must not take Topamax, unless you use highly effective contraception (birth control) during your treatment. See below under ‘Pregnancy and breast-feeding – Important advice for women’.

Treatment of epilepsy
- You must not use Topamax if you are pregnant, unless no other treatment gives sufficient seizure control for you.
- If you are a woman who is able to become pregnant, you must not take Topamax unless you use highly effective contraception (birth control) during your treatment. The only exception is if Topamax is the only treatment giving you sufficient seizure control and you are planning to become pregnant. You must speak to your doctor to make sure you have received information about the risks of taking Topamax during pregnancy and the risks of seizures during pregnancy. See below under ‘Pregnancy and breast-feeding – Important advice for women’.

Make sure you read the patient guide that you will receive from your doctor or scan the QR code for it (see section 6 ‘Other sources of information’).

A patient card is provided with the Topamax package to remind you of the risks in pregnancy.

If you are not sure if the above apply to you, talk to your doctor or pharmacist before using Topamax.

Warnings and precautions

Talk to your doctor before taking Topamax if you:
- have kidney problems, especially kidney stones, or are getting kidney dialysis
- have a history of blood and body fluid abnormality (metabolic acidosis)
- have liver problems
- have eye problems, especially glaucoma
- have a growth problem
- are on a high fat diet (ketogenic diet)
- are a woman who is able to become pregnant. Topamax can harm an unborn child when taken during pregnancy. Highly effective contraception (birth control) must be used during your treatment and for at least 4 weeks after the last Topamax dose. See section ‘Pregnancy and breast-feeding’ for further information.
- are pregnant. Topamax can harm an unborn child when taken during pregnancy.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Topamax.

If you have epilepsy, it is important that you do not stop taking your medicine without first consulting your doctor.

You should also talk to your doctor before taking any medicine containing topiramate that is given to you as an alternative to Topamax.

You may lose weight if you use Topamax so your weight should be checked regularly when using this medicine. If you are losing too much weight or a child using this medicine is not gaining enough weight, you should consult your doctor.

A small number of people being treated with anti-epileptic medicines such as Topamax have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Topamax can cause serious skin reactions, tell your doctor immediately if you develop a skin rash and/or blisters (see also section 4 ‘Possible side effects’).

Topamax may in rare cases cause high levels of ammonia in the blood (seen in blood tests) which can lead to a change in brain function, especially if you are also taking a medicine called valproic acid or sodium valproate.
Since this may be a severe condition, tell your doctor immediately if the following symptoms occur (see also section 4 ‘Possible side effects’):
- difficulty thinking, remembering information, or solving problems
- being less alert or aware
- feeling very sleepy with low energy

At higher doses of Topamax, the risk of developing these symptoms may increase.

Other medicines and Topamax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Topamax and certain other medicines can affect each other. Sometimes the dose of some of your other medicines or Topamax will have to be adjusted.

Especially, tell your doctor or pharmacist if you are taking:
- other medicines that impair or decrease your thinking, concentration, or muscle coordination (e.g. central nervous system depressant medicines such as muscle relaxants and sedatives).
- hormonal contraceptives. Topamax may make hormonal contraceptives less effective. An additional barrier method of contraception such as a condom or pessary/diaphragm should be used. You should talk to your doctor about the best kind of contraception to use while you are taking Topamax.

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

Keep a list of all the medicines you take. Show this list to your doctor and pharmacist before you start a new medicine.

Other medicines you should discuss with your doctor or pharmacist include other anti-epileptic medicines, digoxin, risperidone, lithium, hydrochlorothiazide, metformin, pioglitazone, glibenclamide, amitriptyline, haloperidol, propranolol, diltiazem, venlafaxine, flunarazine, St. John’s wort (Hypericum perforatum) (a herbal preparation used to treat depression), warfarin used to thin the blood.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Topamax.

Topamax with food and drink

You can take Topamax with or without food. Drink plenty of fluids during the day to prevent kidney stones while taking Topamax. You should avoid drinking alcohol when taking Topamax.

Pregnancy and breast-feeding
Important advice for women who are able to become pregnant
Topamax can harm an unborn child. If you are a woman who is able to become pregnant, talk to your doctor about other possible treatments. Visit your doctor to review your treatment and discuss the risks at least once a year.

Migraine prevention:
- For migraine, you must not use Topamax if you are pregnant.
- For migraine, you must not use Topamax if you are a woman who is able to become pregnant unless you are using highly effective contraception.
- Before the start of treatment with Topamax a pregnancy test should be performed in a woman who is able to become pregnant.

Treatment of epilepsy:
- For epilepsy, you must not use Topamax if you are pregnant, unless no other treatment gives sufficient seizure control for you.
- For epilepsy, you must not use Topamax if you are a woman who is able to become pregnant unless you are using highly effective contraception. The only exception is if Topamax is the only treatment giving you sufficient seizure control, and you are planning to become pregnant. You must speak to your doctor to make sure you have received information about the risks of taking Topamax during pregnancy and about the risks of seizures during pregnancy, which may put you or your unborn child at risk.
- Before the start of treatment with Topamax a pregnancy test should be performed in a woman who is able to become pregnant.

The risks of topiramate when taken during pregnancy (irrespective of the disease for which topiramate is used):
There is a risk of harm to the unborn child if Topamax is used during pregnancy.
- If you take Topamax during pregnancy, your child has a higher risk for birth defects. In women who take topiramate, around 4-9 children in every 100 will have birth defects. This compares to 1-3 children in every 100 born to women who do not have epilepsy and do not take an antiepileptic treatment. Particularly, cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth) have been observed. Newborn boys may also have a malformation of the penis (hypospadia). These defects can develop early in pregnancy, even before you know you are pregnant.
- If you take Topamax 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.
- If you take Topamax 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 weighted less 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.

Need for contraception in women who are able to become pregnant:
- If you are a woman who is able to become pregnant, talk to your doctor about other possible treatments instead of Topamax. If the decision is made to use Topamax, you must use highly effective contraception during your treatment and for at least 4 weeks after the last Topamax dose.
- 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) must be used. Talk to your doctor about what contraception is most appropriate for you.
- If you are taking hormonal contraceptives, there is the possibility of reduced effectiveness of the hormonal contraceptive due to topiramate. Therefore, an additional barrier contraceptive method (such as a condom or pessary/diaphragm) should be used.
- Tell your doctor if you experience irregular menstrual bleeding.

Use of Topamax in girls:
If you are a parent or a caregiver of a girl treated with Topamax, you must contact her doctor immediately once your child experiences her first period (menarche). The doctor will inform you about the risks to an unborn child due to topiramate exposure during pregnancy, and the need for using highly effective contraception.

If you wish to become pregnant while taking Topamax:
- Schedule an appointment with your doctor.
- Do not stop using your contraception until you have discussed this with your doctor.
- If you take Topamax for epilepsy, do not stop taking it until you have discussed this with your doctor, because your illness may become worse.
- Your doctor will reassess your treatment and evaluate alternative treatment options. The doctor will counsel you about the risks of Topamax during pregnancy. He/she may also refer you to another specialist.

If you have become pregnant or think you may be pregnant while taking Topamax:
- Schedule an urgent appointment with your doctor.
- If you are taking Topamax to prevent migraine, stop taking the medicine straight away, and contact your doctor to evaluate if you need alternative treatment.
- If you are taking Topamax 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.
- Your doctor will reassess your treatment and evaluate alternative treatment options. The doctor will counsel you about the risks of Topamax during pregnancy. He/she may also refer you to another specialist.
- If Topamax is used during pregnancy, you will be monitored closely to check how your unborn child is developing.

Make sure you read the patient guide that you will receive from your doctor. The patient guide is also available by scanning a QR code, see section 6 ‘Other sources of information’. A patient card is provided with the Topamax package to remind you of topiramate risks in pregnancy.

Breast-feeding
The active substance in Topamax (topiramate) passes into human milk. Effects have been seen in breastfed babies of treated mothers, including diarrhoea, 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.
- Girls and women who are able to become pregnant:
  Topamax treatment should be started and supervised by a doctor experienced in the treatment of epilepsy or migraine. Visit your doctor to review your treatment at least once a year.

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 (hyperammonaemia), which can lead to a change in brain function (hyperammonaemic 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 (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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance
E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TOPAMAX

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.
Store in the original package to protect the tablets from moisture.

Do not throw away any medicines via wastewater or household waste.
Ask your pharmacist how to throw away medicines you no longer use.
These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Topamax contains

- The active substance is topiramate.
- Each Topamax film-coated tablet contains 100 mg of topiramate.
- The other ingredients of Topamax are:
  - core tablet: lactose monohydrate, pregelatinised maize starch, microcrystalline cellulose, sodium starch glycolate (Type A), magnesium stearate
  - film-coating: OPADRY® yellow[1], carnauba wax

[1]OPADRY® contains hypromellose, macrogol, polysorbate 80 and as colourants titanium dioxide E171, iron oxide yellow E172.

What Topamax looks like and contents of the pack

Yellow round tablets, 9 mm in diameter, “TOP” on one side, “100” on the other side.

Blister pack of an aluminium/aluminium foil in strips. Pack sizes of 60 tablets. Individual (alu/alu) blister strips are packed inside a folding box.

Manufacturer:
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Denmark, Finland, Iceland, Norway, Sweden:	Topimax
France:	Epitomax
Greece:	Topamac

This leaflet was last revised in 10/2026.

Other sources of information

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

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone +31 722029365 and ask for help.