

TOPAMAX[®]

TOPAMAX[®]

Tablets and Sprinkle Capsules

Topiramate

What is in this leaflet

This leaflet answers some common questions about TOPAMAX tablets and Sprinkle capsules. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TOPAMAX against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What TOPAMAX is used for

The name of your medicine is TOPAMAX. It contains the active ingredient topiramate. TOPAMAX belongs to a group of medicines known as antiepileptics. TOPAMAX is used for the treatment of various types of seizures in adults and children, aged 2 years and over. It can also be used for the prevention of migraines in adults. TOPAMAX is not used to treat severe migraines that come on suddenly (acute).

It prevents seizures and migraines by acting on the nerves and chemicals in the brain.

Your doctor may prescribe TOPAMAX on its own, or in addition to another medicine for controlling your seizures.

Your doctor may have prescribed TOPAMAX for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you take TOPAMAX

When you must not take it

Do not take TOPAMAX if you have an allergy (hypersensitivity) to:

- Topiramate
- any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.
- if the tablets or capsules are not as described under Product Description at the end of this leaflet.

Symptoms of an allergic or hypersensitivity reaction may include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

Serious skin reactions (Stevens Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)) have been reported in patients receiving TOPAMAX (see ‘Tell Your Doctor Immediately If You Have’ section below).

Do not take TOPAMAX if the packaging is torn or shows signs of tampering. Do not take TOPAMAX after the expiry date printed on the pack has passed.

Before you start to take it

You must tell your doctor if you:

- are pregnant or planning to become pregnant. Topamax has caused harm to the developing foetus when administered to a pregnant woman. Its safety has not been verified in pregnant humans. Information available indicates that there is an association between the use of Topamax in humans during pregnancy, and birth defects including cleft lip/palate. There is an increased risk of early birth and delivery associated with the use of anti-epileptic drugs including topiramate. SGA (a baby who is smaller than the usual) has also been observed in all doses. the prevalence of SGA for women who continued topiramate use later in pregnancy is higher compared to women who stopped its use before the third trimester.
 - However, it is very important to control your fits while you are pregnant. If it is necessary for you to take Topamax, your doctor can help you decide whether or not to take it during pregnancy.
 - are breast feeding or wish to breastfeed. TOPAMAX may appear in breast milk and it is not recommended to breastfeed while taking TOPAMAX. Loose watery stools and sleepiness have been reported in breastfed infants whose mothers receive topiramate treatment. Contact your doctor if you have any concerns
 - have or have ever had a personality disorder or mental illness
 - have or have ever had kidney stones, kidney disease or have a family history of kidney stones
 - have or have ever had liver disease
 - have eye problem or high pressure in the eye
 - have a history of metabolic acidosis (too much acid in the blood, which may cause an increased rate of breathing).
- 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 ‘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.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking TOPAMAX.

Your doctor will advise you whether or not to take TOPAMAX or if you need to adjust the dose or adapt your treatment.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food store.

In particular, tell your doctor or pharmacist if you are taking:

- other medicines for epilepsy, such as phenytoin or carbamazepine
- digoxin (used to treat heart disease)
- oral contraceptives (the pill)
- metformin, pioglitazone or glibenclamide (used to treat diabetes)
- lithium or risperidone (used to treat bipolar disorder and schizophrenia)
- haloperidol (used to treat psychoses)
- hydrochlorothiazide (used to treat swelling or high blood pressure)
- propranolol (used in high blood pressure, some heart conditions, tremors, tumor or migraine headaches)
- diltiazem (used to treat hypertension and prevent angina)
- valproic acid (used to treat epilepsy or mood disorders)
- amitriptyline (used to treat depression)
- flunarizine
- warfarin and other similar medicines called vitamin K antagonists (used to thin the blood)
- any medicine which slows your reactions (CNS depressants). This may include medicines to help you sleep or relieve pain, antidepressants, tranquilisers or antihistamines which can make you drowsy.

These medicines may be affected by TOPAMAX or may affect how well TOPAMAX works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

How to take TOPAMAX

How to take it

Follow your doctor’s instructions about when and how to take TOPAMAX.

You can take the tablets or capsules with or without food. Always swallow the tablets whole with plenty of water. TOPAMAX Sprinkle capsules are available for people who cannot swallow tablets. These capsules can be opened and all of the contents sprinkled onto a teaspoon of soft food which does not require chewing. This mixture should be swallowed immediately and not chewed. It should not be stored for future use. The capsules can also be swallowed whole with water.

The doses shown below are the usual recommended doses. However, your doctor may tell you to take higher or lower doses. Your doctor will start with a low dose and slowly increase the dose to the lowest amount needed to control your epilepsy.

At the start of treatment TOPAMAX may be taken once a day, preferably at night. After the dose is increased, it is taken twice a day. You should continue taking TOPAMAX until your doctor tells you to stop. Before stopping, it is recommended that the dose be reduced gradually.

Adults

Epilepsy

Treatment starts at a low dose of 25 mg to 50 mg per day. The dose is then gradually increased by 25 mg to 100 mg over weekly periods or longer, until the most suitable dose is reached.

Migraine

Treatment starts at a low dose of 25 mg nightly for one week. The dose is then increased over weekly periods or longer by 25mg/day, until the most suitable dose is reached.

Children (2 years and over) - epilepsy only

Treatment starts at 25 mg or less per day, depending on the body weight. This dose is then gradually increased over weekly periods or longer, until the most suitable dose is reached.

If you forget to take it

- Take your dose as soon as you remember, and then continue to take it as you would normally.
- If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
- Do not take a double dose to make up for the dose you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

In case of overdose, immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident & Emergency at your nearest hospital for proper drug toxicity treatment.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much TOPAMAX, you may experience headache, dizziness, light-headedness, drowsiness, convulsions, speech disturbances, double or blurred vision, difficulty with thinking, abnormal coordination, stomach pain, depression, agitation, faster breathing or you may lose consciousness.

While you are using TOPAMAX

Things you must do

- Drink plenty of water. TOPAMAX has been known to cause kidney stones and drinking water may help prevent this.
- Always follow your doctor’s instructions carefully.
- If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking TOPAMAX.
- Tell your doctor if you become pregnant while taking TOPAMAX.

Things you must not do

- Do not suddenly stop taking TOPAMAX without checking with your doctor.
- Do not drink alcohol.
- Do not drive or operate machinery until you know how the medicine affects you.

- Do not use TOPAMAX to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else to use.

Things to be careful of

Changes to your medication

If you are seizure free or your seizures are well controlled, a reduction in your dose, discontinuation or substitution of your current medication should first be assessed by your doctor and pharmacist, and any changes should be implemented gradually.

Effects on thoughts and behaviour

Medicines used to treat epilepsy can increase the risk of suicidal thoughts and behaviour. If you experience feelings of deep sadness and unworthiness (depression) or a worsening of these feelings, any unusual changes in your mood or the emergence of suicidal thoughts, behaviour or thoughts of self-harm, you should report this to your doctor immediately.

Decreased sweating and elevation in body temperature

TOPAMAX may cause decreased sweating and increased body temperature (fever). People, especially children, should be watched for signs of decreased sweating and fever, especially in hot temperatures. Some people may need to be hospitalized for this condition. Call your healthcare provider right away if you have a high fever, a fever that does not go away, or decreased sweating.

Effects on driving and operating machinery

TOPAMAX may cause drowsiness, dizziness or other symptoms which could affect your ability to drive or operate machinery. It may also cause visual disturbances and/ or blurred vision. Make sure you know how you are affected by this medicine before you drive or use machinery.

Particular care is recommended when you first start taking TOPAMAX or if the amount of TOPAMAX or any other medicine you are taking is increased or decreased.

Effects of food and alcohol

TOPAMAX can be taken with or without food. Do not drink alcohol while taking TOPAMAX. Alcohol may increase the risk of unwanted side effects, such as drowsiness.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if any of the following continue or worry you:

- dizziness
- decrease in appetite or weight loss
- itchy skin or skin rash
- inability to sleep
- tingling and numbness of hands and feet (pins and needles)
- nausea, diarrhoea, vomiting or constipation
- abdominal pain or discomfort
- ear pain, buzzing or ringing in ears, deafness

Tell your doctor as soon as possible if you have any of the following as you may need medical attention:

- depression
- nervousness or feeling anxious
- mood alterations such as aggression, agitation or anger
- disturbance in attention
- difficulty with memory or memory impairment
- slowing of thought processes
- abnormal behaviour
- expressive language disorder
- difficulty in speaking
- balance disorder
- co-ordination problems
- unusual hair loss or thinning
- abnormal frequent urination
- decreased feeling or sensitivity, especially in the skin
- fever or high temperature
- decreased or lack of sweating or overheating (mainly in children)
- unusual weakness
- taste disturbance or loss of taste

Tell your doctor immediately if you have:

- unusual tiredness, drowsiness, irritability or lack of energy
 - difficulty breathing, fast or irregular heartbeat or tightening of chest
 - thoughts of harming yourself or thoughts of suicide
 - kidney stones
 - pain when passing urine
 - sudden changes in your eyesight (e.g. blurred vision, double vision or loss of vision) or rapid uncontrollable movements of the eyes
 - eye pain or increased pressure in eye
 - unexplained bleeding or bleeding more frequently
 - severe blisters and bleeding in mucosal sites (such as lips, eyes, mouth, nose, genitals) called Stevens Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). If SJS or TEN are suspected, use of TOPAMAX should be discontinued.
 - 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).
- Untreated acidity (metabolic acidosis) in the blood may increase the risk of kidney stone.
- These are serious side effects. You may need urgent medical attention. Serious side effects are rare.
- Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After using TOPAMAX

Storage

- Keep TOPAMAX tablets or capsules in the original pack until it is time to take them.
- Keep TOPAMAX tablets at or below 30°C.
- For TOPAMAX Sprinkle capsules, do not store above 25°C. Keep the container tightly closed in order to protect from moisture. Do not store the drug/food mixture.
- Do not store TOPAMAX or any medicine in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.
- Keep TOPAMAX where children cannot reach it. A locked cupboard at least one and a half metres (1.5 m) above the ground is a good place to store medicines.

Disposal

- If your doctor tells you to stop taking TOPAMAX, or your medicine has passed its expiry date, ask your pharmacist what to do with any tablets or capsules which may be left over.

Product description

What it looks like

Tablets

TOPAMAX tablets are available in bottle of 60 tablets with desiccant or blister packs (alu/alu) of 60 tablets:

- 25 mg tablets are round and white and marked “TOP” on one side and “25” on the other.
- 50 mg tablets are round and light yellow and marked “TOP” on one side and “50” on the other.
- 100 mg tablets are round and yellow and marked “TOP” on one side and “100” on the other.

Capsules

TOPAMAX Sprinkle capsules are available in bottles of 20, 28, 50, 60 or 100 sprinkle capsules. The capsules consist of a clear cap and a white body. They contain white to off-white spheres.

- 25 mg capsules are marked “TOP” on the cap and “25 mg” on the body.
- 50 mg capsules are marked “TOP” on the cap and “50 mg” on the body.

Ingredients

Tablets

- contain 25, 50 or 100 mg of topiramate per tablet.
- the tablets also contain lactose monohydrate, pregelatinized starch, carnauba wax, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, titanium dioxide, hypromellose, polyethylene glycol and polysorbate. In addition, TOPAMAX 50 mg and 100 mg tablets contain Synthetic iron oxides.

Capsules

- contain 25 or 50 mg of topiramate per capsule.
- the capsules consist of sugar spheres, povidone and cellulose acetate, enclosed in a gelatin capsule.
- the capsule shells contain gelatin, sodium lauryl sulfate, sorbitan monolaurate and titanium dioxide (for the white, opaque body), and are imprinted with black ink.

Version number

22 October 2019

Manufactured by

Tablets

Cilag AG, Schaffhausen, Switzerland

Capsules

Janssen-Ortho LLC, Gurabo, Puerto Rico, USA

Marketing authorization number and date of authorization

Product	Market Authorization Number	Date of Authorization
TOPAMAX [®] (25 MG)	1C 210/41 (N)	30 July 1998
TOPAMAX [®] (50 MG)	1C 211/41 (N)	30 July 1998
TOPAMAX [®] (100 MG)	1C 212/41 (N)	30 July 1998
TOPAMAX [®] SPRINKLE CAPSULES (25 MG)	1C 15003/60 (N)	3 January 2018
TOPAMAX [®] SPRINKLE CAPSULES (50 MG)	1C 15002/60 (N)	3 January 2018

Imported by

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com

Please see full prescribing information at <https://ndi.fda.moph.go.th/>.

<https://www.fda.moph.go.th/sites/oss/Pages/Main.aspx>

Warnings

- 1) This drug may cause somnolence. Should not drive or operate machinery and should not drink alcohol or alcohol-containing beverage while using this drug.
- 2) This drug may cause blood cell abnormality.
- 3) Must not use this drug in pregnant women since it may cause defective infant.
- 4) Should use this drug with caution in patients with liver, kidney disease.
- 5) This drug may cause acute myopia (shortsightedness) and secondary angle closure glaucoma (blockage of fluid in eye causing increased pressure in the eye, pain, or decreased vision).
- 6) If using this drug and the eye abnormalities occur, i.e. blurred vision or eye pain, stop using the drug immediately and consult the doctor.
- 7) Should drink sufficient water every day to prevent kidney stone.