

The medicine is dispensed with a doctor's prescription only

Name of the preparation and its form:

Topamax® 25 Topamax® 50 Topamax® 100 Topamax® 200

Film-coated tablets

The active ingredient and its quantity:			
Each tablet contains: Topiramate 25 mg	Each tablet contains: Topiramate 50 mg	Each tablet contains: Topiramate 100 mg	Each tablet contains: Topiramate 200 mg

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is not intended for infants and children under 2 years of age or as monotherapy under 7 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for:

- Treatment of seizures. For use in combination with other medicines in adults and children from 2 years of age and above, or as monotherapy in adult patients and in children aged 7 years and above.
- Prevention of migraine in adults. The preparation is not intended for alleviating pain during a migraine attack.

Therapeutic group: Antiepileptics

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive to the active ingredient or to any of the additional ingredients contained in the medicine, listed in section 6.
- To prevent migraine if you are pregnant or if you are of childbearing age and do not use effective contraception.

Special warnings regarding use of the medicine

- Do not use the medicine without consulting the doctor before commencing treatment if:**
 - You suffer from kidney problems, especially kidney stones, or you are a patient being treated with dialysis
 - You suffer from a history of problems related to blood and body fluids (metabolic acidosis)
 - You suffer from liver problems
 - You suffer from eye problems (especially glaucoma)
 - You suffer from growth problems
 - You are on a ketogenic diet (a low-carbohydrate, high-fat diet)
 - You are pregnant or are of childbearing age (see section "Pregnancy and breastfeeding" for further information)

If any of the conditions above apply to you, speak with the doctor before using the medicine.

- It is important that you do not stop taking the medicine without first consulting the doctor.
- Do not take any other medicine containing topiramate, given to you as a substitute for this medicine, without first consulting the doctor.
- You may lose weight while using Topamax. Weigh yourself regularly during the course of treatment with Topamax. If you lose a lot of weight or if a child being treated with Topamax does not gain enough weight, consult the doctor.
- In a small number of patients treated with antiepileptics such as Topamax, suicidal thoughts or suicidal behavior have been reported. In case suicidal thoughts occur, refer to the doctor immediately!
- Topamax can cause serious skin side effects. Tell your doctor immediately if you develop a skin rash and/or blisters.
- 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, mainly when given in combination with valproic acid or sodium valproate. Since this may be a severe condition, refer to the doctor immediately if the following symptoms occur:
 - Difficulty thinking, remembering information, or solving problems
 - Sensation of less alertness/vigilance
 - Feeling of sleepiness and a lack of energy

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

Children and adolescents

The side effects in children are generally similar to those in adults. However, the side effects specified in the section "Side effects in children" may be more common in children than in adults.

Tests and follow-up

A pregnancy test should be performed before starting treatment with Topamax.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Topamax and other medicines can affect each other. The doctor will consider whether the dosage of Topamax or of your other medicines needs to be adjusted.

In particular, inform the doctor or pharmacist if you are taking:

- Other medicines that affect or decrease your level of thinking, concentration or muscle coordination (e.g., central nervous system depressants such as muscle relaxants and sedative and sleep medicines).
- Birth control pills. Topamax may impair the effectiveness of birth control pills. Talk to your doctor about the most suitable type of contraception to use during treatment with Topamax. Tell the doctor if you experience changes in your menstrual cycle while using contraception and Topamax.

Make a list of all the medicines you are taking and show this list to your doctor or pharmacist each time before you start taking a new medicine.

The following medicines should also be discussed with your doctor or pharmacist:

- Other antiepileptics
- Risperidone (for the treatment of schizophrenia)
- Lithium (for the treatment of manic depression)
- Hydrochlorothiazide, propranolol, diltiazem (for the treatment of heart problems and to lower blood pressure)
- Metformin, pioglitazone, glibenclamide (for the treatment of diabetes)
- Amitriptyline, venlafaxine (for the treatment of depression)
- Flunarizine (for the prevention of migraines and for the treatment of vertigo)
- Hypericum perforatum* (St. John's wort – a herbal medicine to treat depression)
- Warfarin for thinning the blood

Use of the medicine and food

Topamax may be taken with or without food.

Be sure to drink plenty of fluids during the course of treatment (to reduce the risk of formation of kidney stones).

Use of the medicine and alcohol consumption

Abstain from drinking alcohol during the course of treatment with the medicine.

Uncommon side effects – effects that occur in 1-10 in 1,000 users

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

Rare side effects – effects that occur in 1-10 in 10,000 users

- Glaucoma (blockage of fluid in the eye causing increased pressure in the eye, pain or decreased vision)
- Difficulty thinking, remembering information or solving problems, lack of alertness/vigilance, feeling very sleepy and lacking 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 reactions may appear as a rash with or without blisters, skin irritation, sores and swelling in the mouth, throat, nose, eyes and around the genitals. The skin rash may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life-threatening consequences.

Additional side effects, whose frequency is unknown (effects whose frequency has not yet been determined):

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

Additional side effects, of which the doctor should be informed if they worsen:

Very common side effects – effects that occur in more than 1 user in 10

- Stuffy, runny nose, sore throat
- Tingling, pain and/or numbness of various body parts
- Tiredness or sleepiness
- Dizziness
- Diarrhea
- Nausea
- Weight loss

Common side effects – effects that occur in 1-10 in 100 users

- Anemia (low blood count)
- Allergic reaction (such as skin rash, redness, itching, facial swelling, hives)
- Decreased appetite or loss of appetite
- Aggression, anxiety, anger, abnormal behavior
- Difficulty falling or staying asleep
- Problems with speech, speech disorder, slurred speech
- Clumsiness or lack of coordination, feeling of unsteadiness when walking
- Decreased ability to complete routine tasks
- Decreased/loss of/absence of sense of taste
- Involuntary trembling
- Rapid, uncontrollable movements of the eyes
- Visual disturbances such as double vision, blurred vision, decreased vision, difficulty focusing
- Sensation of spinning (vertigo), ringing in the ears, ear pain
- Shortness of breath
- Cough
- Nosebleed
- Fever
- Weakness
- General unwell feeling
- Vomiting
- Constipation
- Abdominal pain or discomfort
- Indigestion
- Stomach or intestinal infection
- Dry mouth
- Hair loss
- Itching
- Joint pain or swelling
- Muscle cramps or muscle spasms, muscle aches or weakness
- Chest pain
- Weight gain

Uncommon side effects – effects that occur in 1-10 in 1,000 users

- Abnormal blood count, including a decrease in the amount of white blood cells (that help protect against infection) or platelets (blood cells that help stop bleeding) or an increase in the amount of eosinophils (a type of white blood cell)
- Low potassium levels in the blood
- Increased level of liver enzymes
- Swollen glands in the neck, armpit, or groin
- Increased appetite
- Elevated mood
- Hearing, seeing, or feeling things that do not exist, severe mental disorders (psychosis)
- Feeling or displaying apathy, unusual suspiciousness, panic attacks
- Problems with reading, speech disorders, writing problems
- Restlessness or hyperactivity
- Slowed thinking, decreased wakefulness or alertness
- Slow body movements or reduced mobility
- Involuntary abnormal or repetitive muscle movements
- Fainting
- Impaired or abnormal 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

- Eye problems including dry eyes, sensitivity of the eyes to light, involuntary eyelid twitching, watery eyes
- Decreased or loss of hearing, loss of hearing in one ear
- Unusual or slow heartbeat, palpitations
- Low blood pressure or drop in 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)
- Hot flushes, feeling warm
- Pancreatitis
- Flatulence, heartburn, feeling of bloating or fullness
- Bleeding gums, increased production of saliva, drooling, bad breath
- Thirst and drinking large amounts of fluids
- Skin discoloration
- Muscle stiffness, side pain
- Blood in urine, urinary incontinence, a sense of urgency in urination, pain in the kidney area
- Sexual dysfunction, difficulty getting or keeping an erection
- Flu-like illness
- Cold sensation in the fingers and toes

- Feeling drunk
- Learning difficulties

Rare side effects – effects that occur in 1-10 in 10,000 users

- Abnormally elevated mood
- Loss of consciousness
- Blindness in one eye, temporary blindness, night blindness
- Lazy eye
- Swelling in and around the eye
- Numbness, tingling and color change (white, blue and red) in fingers and toes when exposed to the cold
- Inflammation of the liver, liver failure
- Bad skin odor
- Discomfort in the arms or legs
- Kidney problems

Additional side effects, whose frequency is unknown (effects whose frequency has not been determined)

- Maculopathy – a disease of the macula area of the eye. This is the small spot in the retina where vision is keenest. If you notice a change or decrease in vision – refer to the doctor.

Side effects in children

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

- Concentration difficulties
- Increased acid level in the blood
- Thoughts of serious self-harm
- Tiredness
- Decreased or increased appetite
- Aggression, abnormal behavior
- Difficulty falling or staying asleep
- Feeling of unsteadiness when walking
- Unwell feeling
- Decrease in potassium levels in the blood
- Showing or feeling no emotion
- Watery eyes
- Slow or unusual heartbeat

Other side effects that may occur in children:

Common side effects – effects that occur in 1-10 in 100 users

- Sensation of spinning (vertigo)
- Vomiting
- Fever

Uncommon side effects – effects that occur in 1-10 in 1,000 users

- Increased eosinophil (a type of white blood cell) level in the blood
- Hyperactivity
- A feeling of warmth
- Learning difficulties

If a side effect occurs, if one of the side effects worsens, or if you suffer from side effects not mentioned in the leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking the link "Report side effects of drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il/

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.

After first opening the bottle, this medicine may be used for 3 months from the date of opening, but no later than the expiry date marked on the package.

Storage:

Do not store above 25°C. Store in the original package and make sure the bottle is tightly closed to protect the tablets from moisture.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Lactose Monohydrate; Microcrystalline Cellulose; Sodium Starch Glycolate; Pregelatinised Starch; Magnesium Stearate; Carnauba Wax
Each Topamax 25 tablet also contains: Opadry White (YS-1-7706-G)
Each Topamax 50 tablet also contains: Opadry Light Yellow (YS-1-6382-G)
Each Topamax 100 tablet also contains: Opadry Yellow (YS-1-6370-G)
Each Topamax 200 tablet also contains: Opadry Pink (YS-1-1456-G)

The lactose monohydrate content in the Topamax 25, 50, 100, 200 mg tablets is: 30.85, 61.70, 123.40, 43.50 mg, respectively.

What does the medicine look like and what are the contents of the package?

Topamax 25 film-coated tablets: a film-coated, round, white-colored tablet, with "TOP" written on one side and "25" on the other side.

Topamax 50 film-coated tablets: a film-coated, round, light yellow-colored tablet, with "TOP" written on one side and "50" on the other side.

Topamax 100 film-coated tablets: a film-coated, round, yellow-colored tablet, with "TOP" written on one side and "100" on the other side.

Topamax 200 film-coated tablets: a film-coated, round, salmon-colored tablet, with "TOP" written on one side and "200" on the other side.

The tablets come in a plastic bottle. Each bottle contains 60 tablets. In each bottle, there is a desiccant – which should not be swallowed.

Registration Holder and Address: J-C Health Care Ltd., Kibbutz Shefayim, 6099000, Israel.

Name of Manufacturer and Address: Cilag AG, Hochstrasse 201 CH-8205, Schaffhausen, Switzerland.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Topamax 25 – 1075529031
Topamax 50 – 1075629032
Topamax 100 – 1075729033
Topamax 200 – 1075829034

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