

TOPAMAX[®] TABLET/SPRINKLE CAPSULE

Topiramate (25mg, 50mg, 100mg /15mg)

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What TOPAMAX[®] is used for

Topamax[®] belongs to a group of medicines called 'antiepileptic medicines'. It is used:

- alone to treat seizures in adults
- with other medicines to treat seizures in adults and children aged 2 years and above
- to prevent migraine headaches in adults

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.

How TOPAMAX[®] works

Although the exact way TOPAMAX[®] works is unknown, it's believed to help 'calm' overexcitable nerve cells in the brain so they don't send out the signals that can cause migraines or seizures.

Before you use TOPAMAX[®]

-When you must not use it

- if you are allergic (hypersensitive) to topiramate or any of the other ingredients of TOPAMAX[®] (listed in section 'Product description')

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using TOPAMAX[®].

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Your doctor will discuss use of contraceptive with you, as well as discussing whether TOPAMAX[®] is

suitable for you. As with other antiepilepsy 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.

Mothers who breast-feed while taking TOPAMAX[®] must tell the doctor as soon as possible if the baby experiences anything unusual. Ask your doctor or pharmacist for advice before taking this medicine.

-Before you start to use it

Talk to your doctor or pharmacist 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 pregnant or could become pregnant (see section 'pregnancy and breastfeeding' for further information)

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using TOPAMAX[®].

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[®] 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.

-Taking other medicines

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

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).
- birth control pills. TOPAMAX[®] may make your birth control pills less effective.

Tell your doctor if your menstrual bleeding changes while you are taking birth control pills and TOPAMAX[®].

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 includes other:

- antiepileptic medicines,
- risperidone, lithium (used as antipsychotics)
- hydrochlorothiazide, propranolol (used to treat high blood pressure)
- metformin, pioglitazone, glyburide (used to treat diabetes)
- amitriptyline, diltiazem (used to treat heart conditions)
- flunarizine (used to treat migraines)

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using TOPAMAX[®].

TOPAMAX[®] contains sucrose/ lactose

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

How to use TOPAMAX[®]

-How much to use

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

Epilepsy – adjunctive therapy

Adults

25 to 50mg nightly for one week. Subsequently at weekly or bi-weekly intervals, dose should be increased by 25 to 50 to 100mg/day and taken in two divided doses.

Children ages 2 and above

5 to 9 mg/kg/day in two divided doses. Titration should begin at 25mg (or less, based on a range of 1 to 3mg/kg/day) nightly for the first week. Dosage should be increased at 1 or 2-weekly intervals by increments of 1 to 3mg/kg/day, to achieve optimal clinical response.

Epilepsy – monotherapy

Adults

Titration should begin at 25mg nightly for 1 week. The dosage should be increased at 1- or 2- week intervals by increment of 25 or 50 mg/day, administered in two divided doses.

The recommended initial target dose for topiramate monotherapy in adults is 100 mg/day and the maximum recommended daily dose is 500 mg. Some patients with refractory forms of epilepsy have tolerated topiramate monotherapy at doses of 1,000 mg/day.

Children ages 2 and above

Begin at 0.5 to 1 mg/kg nightly for the first week. Dosage should be increased at 1- or 2- week intervals by increments of 0.5 to 1 mg/kg/day, administered in two divided doses.

The recommended initial target dose range for topiramate monotherapy in children aged two years and above is 3 to 6 mg/kg/day. Children with recently diagnosed partial onset seizures have received doses of up to 500 mg/day.

Migraine

Adults

100mg/day in two divided doses beginning with 25mg nightly for 1 week. Dosage should be then increased in increments of 25mg/day at 1 week intervals.

TOPAMAX® Tablet

- 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® Sprinkle Capsule

- TOPAMAX® hard capsules may be swallowed whole or may be opened and sprinkled on a teaspoon of soft food of any type. Carefully twist off the clear portion of the capsule.
- Sprinkle all of the capsule's contents onto a spoonful of soft food, taking care to see that the entire prescribed dosage is sprinkled onto the food.
- Be sure to swallow the entire spoonful of the sprinkle/food mixture immediately. Avoid chewing. Drink fluids immediately in order to make sure all of the mixture is swallowed.
- TOPAMAX® can be taken before, during, or after a meal. Drink plenty of fluids during the day to prevent kidney stones while taking TOPAMAX®.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking TOPAMAX® for as long as your doctor recommends.

-If you forget to use it

- 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 use too much (overdose)

- 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®.

While you are using it

-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

Effects on thoughts and behavior

Medicines used to treat epilepsy can increase the risk of suicidal thoughts and behavior. 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, behavior or thoughts of self-harm, you should report this to your doctor immediately.

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.

Side effects

Like all medicines, TOPAMAX® can cause side effects, although not everybody gets them.

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

- Depression (new or worse)
- 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
- 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
- Glaucoma – blockage of fluid in eye causing increased pressure in the eye or pain.

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 behavior
- 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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI/Vaccine Safety)

Storage and Disposal of TOPAMAX®

-Storage

Keep out of the sight and reach of children.

Do not use TOPAMAX® after the expiry date which is on the bottle/carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the bottle tightly closed in order to protect from moisture.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

TOPAMAX® Tablets:

25 mg: White round tablets, 6 mm in diameter, “TOP” on one side, “25” on the other.

50 mg: Light yellow round tablets, 7 mm in diameter, “TOP” on one side, “50” on the other.

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

TOPAMAX® Sprinkle Capsules:

15 mg capsules: Small white to off-white spheres in hard gelatin capsules with white opaque body marked ‘15 mg’ and clear cap marked ‘TOP’.

-Ingredients

-Active ingredients

The active medicine in TOPAMAX® is topiramate.

-Inactive ingredients

TOPAMAX® Tablets

Tablet core

Lactose monohydrate, magnesium stearate, pregelatinized starch, microcrystalline cellulose, sodium starch glycolate

Film-coating

Carnauba wax, hypromellose, polyethylene glycol, polysorbate, synthetic

iron oxides (yellow and pink coating only), titanium oxide.

TOPAMAX® Sprinkle Capsule Sprinkle beads

Cellulose acetate, povidone, sugar spheres.

Gelatin capsules

Gelatin, sodium lauryl sulphate, sorbitan monolaurate, titanium dioxide (for the white, opaque body).

-MAL numbers

TOPAMAX® Tablets:

25mg: MAL20013558AZ

50mg: MAL20013560AZ

100mg: MAL20013561AZ

TOPAMAX® Sprinkle Capsules

15mg: MAL20002447ARZ

Not all pack sizes may be marketed.

Manufacturer

TOPAMAX® Tablets:

Cilag AG

Hochstrasse 201/209

Schaffhausen, Switzerland

TOPAMAX® Sprinkle Capsules:

Janssen Ortho LLC

State Road 933, KM 0.1

Mamey Ward, Gurabo

Puerto Rico, United States

Product Registration Holder

Johnson & Johnson Sdn Bhd

Lot 3 & 5, Jalan Tandang

46050 Petaling Jaya

Selangor, Malaysia

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