

TOPAMAX®

Tablets and Sprinkle Capsules

Topiramate

Consumer Medicine Information

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 or migraines.

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

Do not take TOPAMAX if the packaging is torn or shows signs of tampering. Do not take TOPAMAX after the expiry date (month and year) 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, and neurodevelopmental disorders such as autism spectrum disorders and intellectual disability. 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.
- 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).

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)
- contraceptives such as estrogen-containing or progestin only contraceptives
- 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)
- vitamin K-antagonist anticoagulant medications (such as warfarin)
- amitriptyline (used to treat depression)
- flunarizine
- any medicine which slows your reactions (CNS depressants). This

may include medicines to help you sleep or relieve pain, antidepressants, tranquillisers or antihistamines which can make you drowsy.

- any medicine which may cause kidney stone

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)

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident & Emergency at your nearest hospital.

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

Poisons Information Centre
telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

Keep these numbers handy in case of an emergency.

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.
- If your menstrual bleeding changes while on contraceptives
- 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).

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 in a cool, dry place where the temperature is below 25°C in the

original pack until it is time to take them.

- Keep TOPAMAX Sprinkle capsules in a cool, dry place where the temperature is below 25°C. 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 blister packs of 20 (25 mg only), 30 (50 mg only - sample pack) or 60:

- 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.
- 200 mg tablets are round and salmon coloured and marked "TOP" on one side and "200" on the other.

Capsules

TOPAMAX Sprinkle capsules are available in bottles of 60. The capsules consist of a clear cap and a white body. They contain white to off-white spheres.

- 15 mg capsules are marked "TOP" on the cap and "15 mg" on the body.
- 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, 100 or 200 mg of topiramate per tablet.
- the tablets also contain lactose monohydrate, pregelatinised maize starch, carnauba wax, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, 25 mg strength: Opadry White YS-1-7706-G (ARTG PI No. 2635), 50 mg strength: Opadry Light Yellow YS-1-6382-G (ARTG PI No. 2636), 100 mg strength: Opadry Yellow YS-1-6370-G (ARTG PI No. 2637) and 200mg strength: Opadry Pink YS-1-1456-G (ARTG PI No. 2638)

Capsules

- contain 15, 25 or 50 mg of topiramate per capsule.
- the capsules consist of sugar spheres containing topiramate, sucrose, povidone and cellulose acetate enclosed in a gelatin capsule.
- 15 mg strength: Empty Hard Gelatin Capsule Size 2 White Op/Nat G2HCSR0446 (ARTG PI No. 106893), 25 mg strength: Empty Hard Gelatin Capsule Size 1 White Op/Nat Part # G1HCSR0602 (ARTG PI No. 106866) and 50 mg strength: Empty Hard Gelatin Capsule Size

0 White Op/Nat Part #
G0HCSRR0796 (ARTG PI No.
106894).

Sponsor

JANSSEN-CILAG Pty Ltd
1-5 Khartoum Road, Macquarie Park
NSW 2113
Australia
Telephone: 1800 226 334
NZ Office: Auckland New Zealand
Telephone: 0800 800 806

Australian Registration Numbers:

TOPAMAX Tablets.

Blister packs:

25mg - 62709
50mg - 62710
100mg - 62711
200mg - 62712

TOPAMAX Sprinkle Capsules

Bottle:

15mg - 167729
25mg - 167730
50mg - 167731

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