

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 it is expected to have for you.

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

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

What TOPAMAX is used for

TOPAMAX is used for the treatment of various types of epilepsy in adults and children over 2 years of age, and for the prevention of migraines in adults. 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 to it or to 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.

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.

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. 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

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, glibenclamide (used to treat diabetes)
- acetazolamide (used to treat glaucoma)
- lithium, risperidone (used to treat bipolar disorder and schizophrenia)
- hydrochlorothiazide (used to treat swelling or high blood pressure)
- propranolol
- valproic acid
- diltiazem (used to treat hypertension and prevent angina)
- any medicine which slows your reactions. This may include medicines to help you sleep or relieve pain, antidepressants, tranquillisers 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.

Taking 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 have taken 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, lightheadedness, 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 taking 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

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.

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:

- unusual tiredness, drowsiness, weakness, dizziness

- decrease in appetite or weight loss
- itchy skin or skin rash
- inability to sleep
- headache
- tingling and numbness of hands and feet
- nose bleed
- nausea, diarrhoea, constipation
- taste disturbance or loss of taste.

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

- nervousness or feeling anxious
- disturbance in attention
- difficulty with memory or memory impairment
- slowing of thought processes
- abnormal behaviour
- expressive language disorder
- 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
- unusual weakness
- difficulty in speaking.

Tell your doctor immediately if you have:

- kidney stones
- pain when passing urine
- sudden changes in your eyesight (e.g. blurred or loss of vision) or rapid uncontrollable movements of the eyes.

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 taking TOPAMAX

Storage

- Keep TOPAMAX tablets or capsules in the original pack until it is time to take them.

- Keep TOPAMAX in a cool, dry place where the temperature is below 25°C. Protect from light.
- For TOPAMAX Sprinkle capsules, 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 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, pregelatinised maize starch, carnauba wax, microcrystalline cellulose, sodium starch glycollate, magnesium stearate, titanium dioxide, hypromellose, laurmacrogol 400 and polysorbate 80. In addition, TOPAMAX 50 mg and 100 mg tablets contain iron oxide yellow, and the 200 mg tablets contain iron oxide red.

Capsules

- contain 15, 25 or 50 mg of topiramate per capsule.
- consist of sugar spheres containing topiramate, sucrose, povidone, cellulose acetate, gelatin and titanium dioxide, enclosed in a gelatine capsule.
- the capsule shells contain gelatin and titanium dioxide, and are imprinted with black ink.

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 AUST R
25 mg	62709
50 mg	62710
100 mg	62711
200 mg	62712

TOPAMAX Sprinkle Capsules	Bottle AUST R
15 mg	167729
25 mg	167730
50 mg	167731

This leaflet was prepared in November 2011.