

TOPIRAMATE SANDOZ®

topiramate tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Topiramate Sandoz. 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 risk of you taking Topiramate Sandoz against the benefits it is expected to 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 TOPIRAMATE SANDOZ IS USED FOR

Topiramate Sandoz is used for the treatment of various types of seizures in adults and children, aged 2 years and over.

This medicine can also be used for the prevention of migraines in adults.

Topiramate Sandoz is not used to treat severe migraines that come on suddenly (acute).

Topiramate Sandoz contains the active ingredient topiramate.

Topiramate belongs to a group of medicines known as antiepileptics. It prevents seizures and migraines by acting on the nerves and chemicals in the brain.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE TOPIRAMATE SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- the active ingredient topiramate or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines.

Some of the symptoms of an allergic reaction may include:

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

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

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have ever had any of the following medical conditions:

- a personality disorder or mental illness
- kidney stones, kidney disease or a family history of kidney stones
- liver disease
- eye problem or high pressure in the eye
- metabolic acidosis (too much acid in the blood, which may cause an increased rate of breathing).

Tell your doctor if you are pregnant or plan to become pregnant.

Topiramate Sandoz 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 Topiramate Sandoz 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 this medicine, your doctor can help you decide whether or not to take it during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Topiramate Sandoz may appear in breast milk and it is not recommended to breastfeed while taking this medicine.

If you have not told your doctor about any of the above, tell him/her before you start taking Topiramate Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Topiramate Sandoz may interfere with each other. These include:

- 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, glibenclamide (used to treat diabetes)
- lithium, 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)
- valproic acid (used to treat epilepsy or mood disorders)
- diltiazem (used to treat hypertension and prevent angina)
- 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 Topiramate Sandoz, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE TOPIRAMATE SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

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 Topiramate Sandoz may be taken once a day, preferably at night. After the dose is increased, it is taken twice a day.

You should continue taking Topiramate Sandoz 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 25 mg/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.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Topiramate Sandoz may not work as well and your problem may not improve.

How to take it

You can take the tablets with or without food. Always swallow the tablets whole with plenty of water.

If you forget to take it

Take your dose as soon as you remember, and 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.

This may increase the chance of you getting an unwanted side effect.

If you have missed more than one dose, or are not sure what to do, ask 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 (telephone 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Topiramate Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Topiramate Sandoz, 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 TAKING TOPIRAMATE SANDOZ

Things you must do

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

Things you must not do

- Do not stop taking Topiramate Sandoz without your doctor's permission.
- Do not take Topiramate Sandoz to treat any other complaints unless your doctor says so.
- Do not give your medicine to anyone else, even if their symptoms seem similar to yours.
- Do not drink alcohol.
- Do not drive or operate machinery until you know how the medicine affects you.

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

Topiramate Sandoz 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

Topiramate Sandoz 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 Topiramate Sandoz or if the amount of Topiramate Sandoz or any other medicine you are taking is increased or decreased.

Effects of food and alcohol

Topiramate Sandoz can be taken with or without food.

Do not drink alcohol while taking Topiramate Sandoz. Alcohol may increase the risk of unwanted side effects, such as drowsiness.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Topiramate Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they 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 notice 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 that may require urgent medical attention. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING TOPIRAMATE SANDOZ

Storage

Keep your medicine in the original container until you need to take it.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Topiramate Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Topiramate Sandoz tablets are available in bottles of 60 tablets:

- 25 mg tablets are white, round shaped, film-coated tablets, plain on both sides.
- 50 mg tablets are yellow, round shaped, film-coated tablets, plain on both sides.
- 100 mg tablets are white, round shaped, film-coated tablets, plain on both sides.
- 200 mg tablets are yellow, round shaped, film-coated tablets, plain on both sides.

Ingredients

Active Ingredient:

Each Topiramate Sandoz 25 mg tablet contains 25 mg topiramate.

Each Topiramate Sandoz 50 mg tablet contains 50 mg topiramate.

Each Topiramate Sandoz 100 mg tablet contains 100 mg topiramate.

Each Topiramate Sandoz 200 mg tablet contains 200 mg topiramate.

Inactive Ingredients:

- Lactose monohydrate
- pregelatinised maize starch
- microcrystalline cellulose
- sodium starch glycollate
- magnesium stearate
- titanium dioxide
- hypromellose
- macrogol 400
- polysorbate 80
- iron oxide yellow (50 mg and 200 mg tablets only).

This medicine does not contain sucrose, gluten, tartrazine or any azo dyes.

Supplier

Sandoz Pty Ltd
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Topiramate Sandoz 25 mg tablets: AUST R 135762

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Topiramate Sandoz 200 mg tablets: AUST R 135810