

Topiramate Sandoz®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Topiramate Sandoz?

Topiramate Sandoz contains the active ingredient topiramate. Topiramate Sandoz 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.

For more information, see Section [1. Why am I using Topiramate Sandoz?](#) in the full CMI.

2. What should I know before I use Topiramate Sandoz?

Do not use if you have ever had an allergic reaction to topiramate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Topiramate Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Topiramate Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Topiramate Sandoz?

- Epilepsy (adults): 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.
- Epilepsy (children 2 years and over): 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.
- Migraine (adults): 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.

More instructions can be found in Section [4. How do I use Topiramate Sandoz?](#) in the full CMI.

5. What should I know while using Topiramate Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Topiramate Sandoz• Drink plenty of water• Women who can become pregnant must use highly effective contraception while taking Topiramate Sandoz• Tell your doctor immediately if you notice any of the following: become pregnant or trying to become pregnant, notice changes to your menstrual bleeding while on contraceptives
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Topiramate Sandoz may cause drowsiness, dizziness, visual disturbances and/ or blurred vision. Make sure you know how you are affected by this medicine before you drive or use machinery.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while taking Topiramate Sandoz. Alcohol may increase the risk of unwanted side effects.
Looking after your medicine	<ul style="list-style-type: none">• Keep Topiramate Sandoz in original pack in a cool, dry place where the temperature is below 25°C.

For more information, see Section [5. What should I know while using Topiramate Sandoz?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, Topiramate Sandoz can cause side effects, although not everybody gets them. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment. Some side effects can be serious, and you may require urgent medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Topiramate Sandoz®

Active ingredient(s): *topiramate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Topiramate Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Topiramate Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Topiramate Sandoz?](#)
- [2. What should I know before I use Topiramate Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Topiramate Sandoz?](#)
- [5. What should I know while using Topiramate Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Topiramate Sandoz?

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

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

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

Your doctor may have prescribed Topiramate Sandoz for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I use Topiramate Sandoz?

Warnings

Do not use Topiramate Sandoz if:

- you are allergic to topiramate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
Symptoms of an allergic or hypersensitivity reaction may include: rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing and swelling of the face, lips, tongue or other parts of the body.

- the tablets are not as described under Product details at the end of this leaflet.

Migraine prevention

- You must not take Topiramate Sandoz if you are pregnant.
If you are a woman who can become pregnant, you must not take Topiramate Sandoz, unless you use highly effective contraception (birth control) during your treatment. See below under Pregnancy and breastfeeding.

Treatment of epilepsy

- You must not take Topiramate Sandoz if you are pregnant, unless no other treatment gives sufficient seizure control for you.
If you are a woman who can become pregnant, you must not take Topiramate Sandoz unless you use highly effective contraception (birth control) during your treatment. Do not stop taking Topiramate Sandoz or your contraception until you have discussed this with your doctor. Your doctor will advise you further and make sure you are aware of and understand all of the risks of taking Topiramate Sandoz during pregnancy and the risks of seizures during pregnancy. See below under Pregnancy and breastfeeding.

Check with your doctor if you:

- have any other medical conditions, particularly:
 - 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).
- take any medicines for any other condition

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Topiramate Sandoz.

Your doctor will advise you whether or not to take Topiramate Sandoz or if you need to adjust the dose or adapt your treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Topiramate Sandoz can harm an unborn child. If you are a woman who can become pregnant, talk to your doctor about other possible treatments. Visit your doctor to review your treatment and discuss the risk.

Migraine prevention

- For migraine, you must not use Topiramate Sandoz if you are pregnant.
- For migraine, you must not use Topiramate Sandoz if you are a woman who can become pregnant unless you are using highly effective contraception (birth control).
- Before the start of treatment with Topiramate Sandoz a pregnancy test should be performed in a woman who can become pregnant.

Treatment of epilepsy

- For epilepsy, you must not use Topiramate Sandoz if you are pregnant, unless you and your doctor have agreed that no other treatment gives sufficient seizure control for you.
- For epilepsy, you must not use Topiramate Sandoz if you are a woman who can become pregnant unless you are using highly effective contraception. Do not stop taking Topiramate Sandoz or your contraception (birth control) until you have discussed this with your doctor. Your doctor will make sure you have received information about the risks of taking Topiramate Sandoz during pregnancy and about the risks of seizures during pregnancy, which may put you or your unborn child at risk.
- Before the start of treatment with Topiramate Sandoz a pregnancy test should be performed in a woman who can become pregnant.

The risks of topiramate when taken during pregnancy:

- The risks apply whether topiramate is taken for migraine prevention or treatment of epilepsy.
- There is a risk of harm to the unborn child if Topiramate Sandoz is used during pregnancy.
- If you take Topiramate Sandoz during pregnancy, your child has a higher risk for birth defects, particularly
 - Cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth).
 - Newborn boys may also have a malformation of the penis (hypospadias).

These defects can develop early in pregnancy, even before you know you are pregnant.

- Your child may be smaller and weigh less than expected at birth.
- Your child may have higher risk for autism spectrum disorders, intellectual disabilities, or attention deficit hyperactivity disorder (ADHD).

Talk to your doctor if you have questions about this risk during pregnancy.

Always use highly effective contraception (birth control) recommended by your doctor during your treatment.

Talk to your doctor about the method of birth control that is most appropriate for you. If you are taking hormonal contraceptives, there is the risk for reduced effectiveness of hormonal contraceptives due to topiramate. Therefore, an additional barrier contraceptive method such as a condom or pessary/diaphragm should be used.

You must tell your doctor if you are breastfeeding or intend to breastfeed. Topiramate Sandoz may appear in breast milk and it is not recommended to breastfeed while taking Topiramate Sandoz.

3. What if I am taking other medicines?

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

Some medicines may interfere with Topiramate Sandoz and affect how it works.

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 oestrogen-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 Topiramate Sandoz or may affect how well Topiramate Sandoz works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Topiramate Sandoz.

4. How do I use Topiramate Sandoz?

How much to take

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 prevention

- 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

- 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.

Follow the instructions provided and use Topiramate Sandoz until your doctor tells you to stop.

How to take Topiramate Sandoz

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

When to take Topiramate Sandoz

- 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.
- Topiramate Sandoz should be used as prescribed by your doctor depending on your condition. Follow the instructions provided and use Topiramate Sandoz until your doctor tells you to stop. Before stopping, it is recommended that the dose be reduced gradually

If you forget to use Topiramate Sandoz

Topiramate Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time, 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 use too much Topiramate Sandoz

If you think that you have used too much Topiramate Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while using Topiramate Sandoz?

Things you should do

- Drink plenty of water. Topiramate Sandoz 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 Topiramate Sandoz.
- If you wish to become pregnant while taking Topiramate Sandoz:
 - Schedule an appointment with your doctor.
 - Do not stop using your contraception until you have discussed this with your doctor and do not become pregnant until you have discussed your options with your doctor.

Call your doctor straight away if you:

- notice changes to your menstrual bleeding while on contraceptives
- become pregnant or think you may be pregnant while taking Topiramate Sandoz.
 - If you are taking Topiramate Sandoz for epilepsy, do not stop taking this medicine until you have discussed this with your doctor, as this may worsen your illness. Worsening of your epilepsy may put you or your unborn child at risk.
 - If you are taking Topiramate Sandoz to prevent migraine, stop taking the medicine straight away, and contact your doctor to evaluate if you need alternative treatment.

Remind any doctor, dentist or pharmacist you visit that you are using Topiramate Sandoz.

Things you should not do

- Do not stop using this medicine suddenly without checking with your doctor, unless you become pregnant or think you may be pregnant. See additional information under Section [5. What should I know while using Topiramate Sandoz?](#).
- Do not drink alcohol.

- Do not use Topiramate Sandoz 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

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 hospitalised 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.

Serious skin reactions

Tell your doctor immediately if you develop a skin rash and/or blisters.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Topiramate Sandoz affects you.

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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Keep Topiramate Sandoz tablets in the original pack until it is time to take them.

- Keep Topiramate Sandoz tablets in a cool, dry place where the temperature is below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Metabolism and nutrition-related:</p> <ul style="list-style-type: none"> • decrease in appetite or weight loss <p>Skin-related:</p> <ul style="list-style-type: none"> • itchy skin or skin rash <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> • nausea, diarrhoea, vomiting or constipation • abdominal pain or discomfort <p>Ear-related:</p> <ul style="list-style-type: none"> • ear pain, buzzing or ringing in ears, deafness <p>Psychiatric-related:</p> <ul style="list-style-type: none"> • inability to sleep • mood alterations such as aggression, agitation or anger • expressive language disorder • depression • nervousness or feeling anxious <p>Nervous system-related:</p> <ul style="list-style-type: none"> • dizziness • disturbance in attention • difficulty with memory or memory impairment • slowing of thought processes • abnormal behaviour • difficulty in speaking 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> balance disorder co-ordination problems decreased feeling or sensitivity, especially in the skin tingling and numbness of hands and feet (pins and needles) unusual weakness <p>Other-related:</p> <ul style="list-style-type: none"> unusual hair loss or thinning abnormal frequent urination fever or high temperature decreased or lack of sweating or overheating (mainly in children) ever or high temperature taste disturbance or loss of taste 	
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Serious side effects

Serious side effects	What to do
<p>Nervous system-related:</p> <ul style="list-style-type: none"> unusual tiredness, drowsiness, irritability or lack of energy <p>Respiratory-related:</p> <ul style="list-style-type: none"> difficulty breathing, fast or irregular heartbeat or tightening of chest <p>Psychiatric-related:</p> <ul style="list-style-type: none"> thoughts of harming yourself or thoughts of suicide <p>Kidney-related:</p> <ul style="list-style-type: none"> kidney stones pain when passing urine <p>Vision-related:</p> <ul style="list-style-type: none"> 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 <p>Other-related:</p> <ul style="list-style-type: none"> unexplained bleeding or bleeding more frequently severe blisters and bleeding in mucosal sites (such as lips, eyes, mouth, nose, genitals). 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Topiramate Sandoz contains

Active ingredient (main ingredient)	topiramate
Other ingredients (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).
Potential allergens	sugars (as lactose)

Do not take this medicine if you are allergic to any of these ingredients.

What Topiramate Sandoz looks like

Topiramate Sandoz 25 mg – white, round shaped, film-coated tablets, plain on both sides. Available in bottles of 60 tablets (Aust R 135762).

Topiramate Sandoz 50 mg – yellow, round shaped, film-coated tablets, plain on both sides. Available in bottles of 60 tablets (Aust R 135779).

Topiramate Sandoz 100 mg – white, round shaped, film-coated tablets, plain on both sides. Available in bottles of 60 tablets (Aust R 135794).

Topiramate Sandoz 200 mg – yellow, round shaped, film-coated tablets, plain on both sides. Available in bottles of 60 tablets (Aust R 135810).

Who distributes Topiramate Sandoz

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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