

APO-Topiramate tablets

Contains the active ingredient topiramate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about topiramate. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Topiramate Topiramate. It contains the active ingredient topiramate.

It is used to:

- treat various types of epilepsy in adults and children over 2 years of age
- prevent migraines in adults.

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

Your doctor may prescribe topiramate 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 this medicine for another reason.

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

How it works

Topiramate prevents seizures and migraines by acting on the nerves and chemicals in the brain.

Use in children

This medicine may be used to treat epilepsy only in children aged 2 years or older.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, topiramate or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic

reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - personality disorder or mental illness
 - kidney disease, kidney stones or have a family history of kidney stones
 - liver disease
 - eye problems or high pressure in the eye.
3. You are currently pregnant or you plan to become pregnant. It is very important to control your fits during pregnancy, however, there is evidence topiramate may cause harm to the developing foetus.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with topiramate.

These include:

- 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, tranquilisers or antihistamines which can make you drowsy.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with topiramate.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The doses shown below are the usual recommended doses. However, your doctor may tell you to take higher or lower doses.

ADULTS

Epilepsy - Treatment starts at a dose of 25 mg to 50 mg nightly for one week or longer. The dose is then gradually increased by 25 mg to 100 mg/day over weekly periods or longer, until the most suitable dose is reached.

Migraine - Treatment starts at a 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 child's body weight. The dose is then gradually increased over weekly periods or longer, until the most suitable dose is reached.

How to take it

Swallow the tablets whole with a glass of water. Do not crush or chew the tablets.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately

telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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

If you take too much topiramate 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 this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Drink plenty of water. Topiramate has been known to cause kidney stones and drinking water may help prevent this.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

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

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

Effects of alcohol

Do not drink alcohol while taking topiramate. Alcohol may increase the risk of you experiencing side effects, such as drowsiness.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking topiramate or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- 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 notice any of the following:

- depression
- 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
- decreased or lack of sweating or overheating
- unusual weakness
- difficulty in speaking.

These may be serious side effects. You may need medical attention.

If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- thoughts of harming yourself or thoughts of suicide
- 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
- eye pain or increase pressure in the eye.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to topiramate, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing

- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

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

Do not store your medicine, 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Topiramate looks like

The tablets are available in 4 different strengths:

Topiramate 25 mg tablets

White to off-white, round, unscored, film coated tablet, imprinted "APO" on one side and "TP over "25" on the other side.

Topiramate 50 mg tablets

Light-yellow, round, unscored, film coated tablet, imprinted "APO" on one side and "TP over "50" on the other side.

Topiramate 100 mg tablets

Mustard yellow, round, unscored, film coated tablet, imprinted "APO" on one side and "TP over "100" on the other side.

Topiramate 200 mg tablets

Reddish-brown, round, unscored, film coated tablet, imprinted "APO" on one side and "TP over "200" on the other side.

Blister pack of 60 tablets

Bottle of 60 tablets

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 25 mg, 50 mg, 100 mg or 200 mg of topiramate as the active ingredient.

It also contains the following inactive ingredients:

- methylcellulose
- croscarmellose sodium
- magnesium stearate
- silica-colloidal anhydrous
- hypromellose
- hydroxypropylcellulose
- macrogol
- titanium dioxide
- iron oxide yellow (50 mg & 100 mg only)
- iron oxide red (200 mg only).

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and other azo dyes-free.

Australian Registration Numbers

APO-Topiramate 25 mg tablets
Blister pack of 60 tablets
AUST R: 124729

APO-Topiramate 25 mg tablets
Bottle of 60 tablets
AUST R: 124733

APO-Topiramate 50 mg tablets
Blister pack of 60 tablets
AUST R: 124730

APO-Topiramate 50 mg tablets
Bottle of 60 tablets
AUST R: 124734

APO-Topiramate 100 mg tablets
Blister pack of 60 tablets
AUST R: 124731

APO-Topiramate 100 mg tablets
Bottle of 60 tablets
AUST R: 124735

APO-Topiramate 200 mg tablets
Blister pack of 60 tablets
AUST R: 124732

APO-Topiramate 200 mg tablets
Bottle of 60 tablets
AUST R: 124736

Sponsor

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