

Apo-Topiramate

contains the active ingredient, topiramate

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

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about 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. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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.

Keep this leaflet with your medicine.

You may want to read it again.

What topiramate is used for

The name of your medicine is Apo-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, and for the prevention of migraines in adults.

How it works

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

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 topiramate for another reason.

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

There is no evidence that this medicine is addictive.

Use in children

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

Before you take topiramate

When you must not take it

Do not take this medicine Topiramate if you 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: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

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 or pharmacist.

Before you start to take it

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
- eye problem or high pressure in the eye
- kidney stones, kidney disease or have a family history of kidney stones
- liver disease.

3. You are pregnant or planning to become pregnant.

Topiramate has caused harm to the developing foetus in animal studies. Its safety has not been verified in pregnant humans. However, it is very important to control your fits while you are pregnant.

If it is necessary for you to take topiramate, your doctor can help you decide whether or not to take it during pregnancy.

4. You are breast-feeding or wish to breast-feed.

Topiramate may appear in breast milk and it is not recommended to breast-feed while taking topiramate.

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

Taking other medicines

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

Some medicines and topiramate may interfere with each other. 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)
- venlafaxine (used to treat depression)
- 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 topiramate 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 can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking topiramate.

Other interactions not listed above may also occur.

How to take this medicine

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

They may be different to the information contained in this leaflet.

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

How much to take

Your doctor or pharmacist will tell you how tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

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 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 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.

How to take it

Take it at about the same time each day.

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

You can take the tablets with or without food.

Swallow the tablets whole with a glass of water.

Do not crush or chew the tablets.

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 for your next dose, skip the dose you missed and take your next dose when you are meant to.

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 the dose that 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 (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much topiramate.

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 get one or more of the following symptoms:

- 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 topiramate

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking topiramate.

Tell your doctor immediately if you become pregnant.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

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

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor tells you to.

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

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

Do not drive or operate machinery until you know how the medicine affects you.

Things to be careful of

Suicidal thoughts or behaviours

Treatment with antiepileptic medicines is associated with a risk of suicidal thoughts and behaviour; available data suggest that the increased risk applies to all antiepileptic medicines and may be seen as early as 1 week after starting treatment. However suicidal thoughts and actions can also be from other causes.

There is no need to stop treatment on the basis of this new information unless your doctor says so. Stopping these medicines suddenly can cause serious problems. Anyone who is concerned about their treatment should talk to their doctor first.

Pay close attention to any day-to-day changes in mood, behavior and actions. These changes can happen very quickly so it is important to be mindful of any sudden differences.

Be aware of common warning signs that might be a signal for risk of suicidal behavior. Some of these are:

- Talking or thinking about wanting to hurt one's self or end one's life
- Becoming preoccupied with death and dying
- Becoming depressed or having depression get worse

- Withdrawing from friends and family
- Giving away prized possessions

If any of the above happens seek medical advice 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. 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.

Side effects of topiramate

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

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

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- unusual tiredness, drowsiness, weakness, dizziness
- decrease in appetite or weight loss
- itchy skin or skin rash
- faster breathing
- headache
- unsteady or abnormal way of walking
- tingling and numbness in fingers and toes
- nausea, diarrhoea, increased saliva, altered sense of taste, stomach pain
- difficulty in controlling emotions.

Tell your doctor as soon as possible if you notice any of the following:

- difficulty with concentration or attention; confusion
- difficulty with memory and/or thinking
- depression, mood problems, abnormal thoughts, thoughts of harming yourself

- reduced sweating/overheating (mainly in children) - feeling flushed or overheated more than usual, particularly during exercise or hot weather.
- agitation or unusual nervousness
- co-ordination problems, tremor or slow reaction
- speech or language problems
- effects on eyes or vision (e.g. double vision)
- frequent infections with symptoms such as fever, severe chills, sore throat or mouth ulcers
- sudden severe back or side pain, difficult or painful to pass urine.

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:

- blood in your urine or severe pain in the lower back or genital area
- sudden severe pain in the chest, arms or legs
- sudden changes in your eyesight (e.g. blurred or lost of vision), red eye or eye pain

- abnormal tiredness, dark urine, pale stools, yellowing of the skin or eyes.

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

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

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

After taking this medicine

Storage

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

If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25 degrees 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 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 it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What Apo Topiramate looks like

The tablets are available in 4 different strengths:

Apo-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.

Apo-Topiramate 50 mg tablets

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

Apo-Topiramate 100 mg tablets

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

Apo-Topiramate 200 mg tablets

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

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 50 mg tablets

Blister pack of 60 tablets

AUST R: 124730

Apo-Topiramate 100 mg tablets

Blister pack of 60 tablets

AUST R: 124731

Apo-Topiramate 200 mg tablets

Blister pack of 60 tablets

AUST R: 124732

Sponsor

Apotex Pty Ltd

ABN 52 096 916 418

66 Waterloo Road

North Ryde NSW 2113

Australia

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