

NEW ZEALAND CONSUMER MEDICINE INFORMATION

Topiramate Actavis

Topiramate

Topiramate Tablets 25 mg, 50 mg, 100 mg and 200 mg

What is in this leaflet

This leaflet answers some common questions about TOPIRAMATE - ACTAVIS Tablets.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking TOPIRAMATE - ACTAVIS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

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

What TOPIRAMATE - ACTAVIS is used for

TOPIRAMATE, the active ingredient in TOPIRAMATE - ACTAVIS Tablets, is used for the treatment of various types of epilepsy in adults and children over 2 years of age**, and for the prevention of migraine in adults. It prevents seizures and migraines by acting on the nerves and chemicals in the brain.

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

Your doctor may have prescribed TOPIRAMATE - ACTAVIS for another reason. Ask your doctor if you have any questions about why TOPIRAMATE - ACTAVIS has been prescribed for you.

There is no evidence that TOPIRAMATE - ACTAVIS is addictive.

TOPIRAMATE - ACTAVIS is available only with a doctor's prescription.

*** Topiramate Actavis tablet range cannot deliver lower doses required for younger paediatric patients (See the data sheet for further information on this).*

Before you take TOPIRAMATE - ACTAVIS

When you must not take it

Do not take TOPIRAMATE - ACTAVIS if you are allergic to medicines containing topiramate, or any of the ingredients listed at the end of this leaflet.

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
- lumpy skin rash ("hives"), hayfever or fainting.

Do not take TOPIRAMATE - ACTAVIS if the expiry date (Exp.) printed on the pack has passed. It may not work well if you do.

Do not take TOPIRAMATE - ACTAVIS if the packaging is torn or shows signs of tampering.

Before you start to take it

Certain people must use TOPIRAMATE - ACTAVIS with caution. Ask your doctor for advice.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Topiramate can cause harm to the developing foetus in pregnant women. Information available indicates that infants exposed to topiramate in their mothers' womb have an increased risk of 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 topiramate, your doctor can help you decide whether or not to take it during pregnancy.

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

Topiramate may appear in breast milk and it is not recommended to breastfeed while taking TOPIRAMATE - ACTAVIS.

Tell your doctor if you have, or have had, the following medical problems:

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

Taking other medicines

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

Some medicines may be affected by TOPIRAMATE - ACTAVIS, or may affect how well it works. These include:

- other medicines for epilepsy, such as phenytoin or carbamazepine
- valproic acid (used to control epilepsy or treat mood disorder like mania)
- lithium, risperidone (used to treat bipolar disorder and schizophrenia)
- oral contraceptives (the pill)
- digoxin (used to treat heart disease)
- hydrochlorothiazide (used to treat swelling or high blood pressure)
- propranolol (used to lower blood pressure or treat tremor)
- diltiazem (used to lower blood pressure and prevent angina)
- metformin, pioglitazone, glibenclamide (used to treat diabetes)
- acetazolamide (used to treat glaucoma)
- any medicine which slows your reactions. This may include medicines to help you sleep or relieve pain such as antidepressants, tranquillisers or antihistamines, which all can make you drowsy.

Your doctor can tell you what to do if you are taking any of these medicines. If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking TOPIRAMATE - ACTAVIS.

If you have not told your doctor about any of the above, tell them before you start taking TOPIRAMATE - ACTAVIS.

How to take TOPIRAMATE - ACTAVIS

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

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 condition.

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. Daily doses above 1000 mg are not recommended.

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.

*** Topiramate Actavis tablet range cannot deliver lower doses required for younger paediatric patients (See the data sheet for further information on this).*

How to take it

Swallow TOPIRAMATE - ACTAVIS Tablets whole with plenty of water. You can take them with or without food.

When to take it

At the start of treatment, TOPIRAMATE - ACTAVIS may be taken once a day, preferably at night. After the dose is increased, it is taken twice a day.

Take TOPIRAMATE - ACTAVIS at about the same time of each day.

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

How long to take it

You should continue taking TOPIRAMATE - ACTAVIS until your doctor tells you to stop. Before stopping, it is recommended that the dose be reduced gradually.

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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, 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 National Poisons Information Centre (0800 POISON or 0800 764 766), or go to Accident and Emergency department at your

nearest hospital, if you think that you or anyone else may have taken too many TOPIRAMATE - ACTAVIS Tablets.

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

Keep the telephone numbers for these places handy.

If you take too much TOPIRAMATE - ACTAVIS, 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 - ACTAVIS

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking TOPIRAMATE - ACTAVIS.

Drink plenty of water.

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

If you become pregnant while taking TOPIRAMATE - ACTAVIS, tell your doctor immediately.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

Always follow your doctor's instructions carefully.

Things you must not do

Do not use TOPIRAMATE - ACTAVIS to treat any other conditions unless your doctor tells you to.

Do not change the dose of your TOPIRAMATE - ACTAVIS without checking with your doctor.

Do not suddenly stop taking TOPIRAMATE - ACTAVIS without checking with your doctor.

Do not give TOPIRAMATE - ACTAVIS to anyone else, even if they have the same condition or similar symptoms as you.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking TOPIRAMATE - ACTAVIS until you know how it affects you.

TOPIRAMATE - ACTAVIS can cause drowsiness, dizziness or other symptoms that can 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 - ACTAVIS or if the amount of TOPIRAMATE - ACTAVIS or any other medicine you are taking is increased or decreased.

Avoid alcohol while taking TOPIRAMATE - ACTAVIS.

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 - ACTAVIS.

Like other medicines, TOPIRAMATE - ACTAVIS can cause some side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the 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 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
- inability to sleep
- faster breathing
- headache
- unsteady or abnormal way of walking
- tingling and numbness in fingers and toes
- nose bleed
- 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, as you may need medical care:

- difficulty with concentration or attention; confusion
- difficulty with memory and/or thinking
- depression, mood problems, abnormal thoughts, thoughts of harming yourself
- reduced sweating or 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
- unusual hair loss or thinning
- abnormal frequent urination
- 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.

If any of the following happen after taking TOPIRAMATE - ACTAVIS, stop taking it and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- allergic reactions such as swelling of the face, lips, mouth, tongue or throat that may cause difficulty in swallowing or breathing; pinkish or itchy swellings on the skin (hives or nettle rash)
- blood in your urine or severe lower back pain that spreads towards the groin area
- sudden severe pain in the chest, arms or legs
- sudden changes in your eyesight (e.g. blurred or loss of vision), red eye or eye pain
- abnormal tiredness, dark urine, pale stools, yellowing of the skin or eyes.

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

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using TOPIRAMATE - ACTAVIS

Storage

Keep TOPIRAMATE - ACTAVIS 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.

Keep TOPIRAMATE - ACTAVIS in a cool, dry place where the temperature stays below 25°C.

Keep your tablets in the packs until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Do not store TOPIRAMATE - ACTAVIS or other medicines in the bathroom or near a sink. Do not leave the medicines in the car or on window sills.

Heat, light and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking TOPIRAMATE - ACTAVIS, or your medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What TOPIRAMATE - ACTAVIS looks like

TOPIRAMATE - ACTAVIS Tablets are available in four strengths, supplied in both opaque bottles and foil blister packs of 60 tablets. TOPIRAMATE ACTAVIS 25 mg tablets are also available as sample packs- bottles of 20 tablets. (Not all pack sizes may be available in market)

25 mg – white, round, biconvex, film marked with 'V1'.

50 mg – light yellow, round biconvex, film coated tablet marked with 'V3'.

100 mg – yellow, round biconvex, film coated tablet marked with 'V4'.

200 mg – salmon, oval biconvex, film coated tablet marked with 'V5'.

Ingredients

Each TOPIRAMATE - ACTAVIS Tablet contains:

- 25 mg, 50 mg, 100 mg or 200 mg as the active ingredient
- excipients including mannitol, microcrystalline cellulose, pregelatinised maize starch, magnesium stearate, croscarmellose sodium

- colouring agent Opadry II White 85F18422 for 25 mg Tablets, Opadry II Yellow 85G32312 for 50 mg Tablets, Opadry II Yellow 85G32313 for 100 mg Tablets, and Opadry II Pink 85G34776 for 200 mg Tablets.

Supplier

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