

# Topiramate-Actavis

*Film-coated tablets*

*Topiramate*

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## Consumer Medicine Information (CMI)

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### What is in this leaflet

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This leaflet answers some common questions about Topiramate-Actavis tablets. 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 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 this information again.

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### What Topiramate-Actavis is used for

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

Topiramate-Actavis belongs to a group of medicines known as antiepileptics.

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

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 this medicine has been prescribed for you.

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### Before you take Topiramate-Actavis

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#### ***When you must not take it***

**Do not take Topiramate-Actavis if you have an allergy (hypersensitivity) to:**

- topiramate

- any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.
- if the tablets are not as described under Product Description at the end of this leaflet.

Symptoms of an allergic or hypersensitivity reaction may include:

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

**Do not take Topiramate-Actavis if the packaging is torn or shows signs of tampering.**

**Do not take Topiramate-Actavis after the expiry date (month and year) printed on the pack has passed.**

**For migraine, you must not take Topiramate-Actavis if you are pregnant.**

**For epilepsy, you must not take Topiramate-Actavis if you are pregnant, unless you and your doctor have agreed that no other treatment gives sufficient seizure control for you.**

In epilepsy, do not stop taking Topiramate-Actavis 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-Actavis during pregnancy and about the risks of seizures during pregnancy, which may put you or your unborn child at risk.

#### **Pregnancy and breastfeeding**

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

Topiramate-Actavis 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 at least once a year.

#### ***Migraine prevention***

- For migraine, you must not use Topiramate-Actavis if you are pregnant.
- You must use highly effective contraception (birth control) during your treatment and for at least 4 weeks after stopping treatment with Topiramate-Actavis.

- Before the start of treatment with Topiramate-Actavis a pregnancy test should be performed in a woman who can become pregnant.

### **Treatment of epilepsy**

- For epilepsy, you must not use Topiramate-Actavis if you are pregnant, unless you and your doctor have agreed that no other treatment gives sufficient seizure control for you.
- You must use highly effective contraception (birth control) during your treatment and for at least 4 weeks after stopping treatment with Topiramate-Actavis. Do not stop taking Topiramate-Actavis 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-Actavis 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-Actavis a pregnancy test should be performed in a woman who can become pregnant.

### **Before you start to take it**

#### **You must tell your doctor if you:**

- are pregnant or planning to become pregnant. Topiramate-Actavis 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-Actavis in humans during pregnancy and birth defects including cleft lip/ palate, malformation of the penis. The following can also develop early in pregnancy, even before you know you are pregnant; neurodevelopmental disorders such as autism spectrum disorders, intellectual disability or attention deficit hyperactivity disorder (ADHD). However, it is very important to control your fits while you are pregnant. If it is necessary for you to take Topiramate-Actavis, your doctor can help you decide whether or not to take it during pregnancy.
- are breast feeding or wish to breastfeed. Topiramate-Actavis may appear in breast milk and it is not recommended to breastfeed while taking Topiramate-Actavis.
- 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).

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

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

### **Taking other medicines**

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

**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 estrogen 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 or lamotrigine (used to treat epilepsy or mood disorders)
- 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.
- anticoagulant medications (e.g. warfarin)
- any medicine which may cause kidney stone

These medicines may be affected by Topiramate-Actavis or may affect how well Topiramate-Actavis works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

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## How to take Topiramate-Actavis

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### **How to take it**

**Follow your doctor's instructions about when and how to take Topiramate-Actavis.**

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

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-Actavis 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-Actavis 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.

### **Adults 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 data sheet for further information on this).**

### **If you forget to take it**

- 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 take too much (overdose)**

**Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident & Emergency at your nearest hospital.**

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

Poisons Information Centre telephone number:

- New Zealand: 0800 POISON or 0800 764 766

### **Keep this number handy in case of an emergency.**

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.

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## While you are using Topiramate-Actavis

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### **Things you must do**

- Drink plenty of water. Topiramate-Actavis 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-Actavis.
- If you wish to become pregnant while taking Topiramate-Actavis:
  - 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-Actavis.
  - If you are taking Topiramate-Actavis 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-Actavis 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-Actavis.

## Things you must not do

- Do not suddenly stop taking Topiramate-Actavis without checking with your doctor. Please call your doctor straight away if you become pregnant or think you may be pregnant.
- Do not drink alcohol.
- Do not drive or operate machinery until you know how the medicine affects you.

**Do not use Topiramate-Actavis 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-Actavis 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-Actavis 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-Actavis or if the amount of Topiramate-Actavis or any other medicine you are taking is increased or decreased.

### Effects of food and alcohol

Topiramate-Actavis can be taken with or without food.

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

such as drowsiness.

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## Side effects

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All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some 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 any of the following continue or 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 have 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. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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## After using Topiramate-Actavis

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### Storage

- Keep Topiramate-Actavis tablets in the original pack until it is time to take them.
- Keep Topiramate-Actavis in a cool, dry place where the temperature is below 25°C. Protect from light.
- Do not store Topiramate-Actavis or any medicine in the bathroom or near a sink. Do not leave medicines in the car or on windowsills. Heat and dampness can destroy some medicines.
- Keep Topiramate-Actavis where children cannot reach it. A locked cupboard at least one and a half metres (1.5 m) above the ground is a good place to store 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 tablets which may be left over.

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## Product description

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### What it looks like

Topiramate-Actavis tablets are available in four strengths, supplied in both opaque bottles and foil blister packs of 10, 60 and 200 tablets. Topiramate-Actavis 25 mg tablets are also available as a sample pack - bottles of 20 tablets (Not all pack sizes may be available).

The following strengths are available:

- 25 mg tablets are white, round, biconvex, film coated tablets marked with 'V1'.

- 50 mg tablets are light yellow, round, biconvex, film coated tablets marked with 'V3'.
- 100 mg tablets are yellow, round, biconvex, film coated tablets marked with 'V4'.
- 200 mg tablets are salmon, oval, biconvex, film coated tablets marked with 'V5'.

### Ingredients

- Topiramate-Actavis contain 25, 50, 100 or 200 mg of topiramate per tablet.
- the tablets also contain mannitol, microcrystalline cellulose, pregelatinised maize starch, magnesium stearate, croscarmellose sodium, and the colouring 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.

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## Sponsor

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