

# EPIRAMAX®

topiramate

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about EPIRAMAX.

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 risks and benefits. Your doctor has weighed the expected benefits of you taking EPIRAMAX against the risks this medicine could have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What EPIRAMAX is used for

EPIRAMAX belongs to a group of medicines known as antiepileptics.

EPIRAMAX is used for the treatment of various types of epilepsy in adults and children, aged 2 years and over, and for the prevention of migraines in adults. It 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 have prescribed this medicine on its own or in addition to another medicine for controlling your seizures or migraines.

Your doctor may have prescribed EPIRAMAX for another reason. Ask your doctor if you have any

questions about why this medicine has been prescribed for you.

There is no evidence that EPIRAMAX is addictive.

EPIRAMAX is only available with a doctor's prescription.

### Before you take it

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

**Do not take EPIRAMAX 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 or capsules 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

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

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

- are pregnant or planning to become pregnant. EPIRAMAX 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 EPIRAMAX in humans during pregnancy and birth defects including cleft lip/palate, and neuro-developmental disorders such as autism spectrum disorders and intellectual disability. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take EPIRAMAX, your doctor can help you decide whether or not to take it during pregnancy.

- are breast feeding or wish to breastfeed. EPIRAMAX may appear in breast milk and it is not recommended to breastfeed while taking EPIRAMAX.
- 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 EPIRAMAX.**

Your doctor will advise you whether or not to take EPIRAMAX 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, tumour 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.

These medicines may be affected by EPIRAMAX or may affect how well EPIRAMAX 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 it

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

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

### *How much to take*

Your doctor will decide the right dose for you depending on your medical conditions.

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.

### **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.

**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.

### **Migraine**

**Adults only** - Treatment starts at a low dose of 25 mg nightly for one week. The dose is then increased over weekly periods or longer by 25 mg per day, until the most suitable dose is reached.

### *How to take it*

Swallow the tablet with a glass of water, with or without food.

### *When to take it*

At the start of treatment, EPIRAMAX may be taken once a

day, preferably at night. After the dose is increased, it is taken twice a day.

**Try to take EPIRAMAX at about the same time each day.**

This will have the best effect on your condition. It will also help you to remember when to take it.

### *How long to take it*

**Continue taking EPIRAMAX for as long as your doctor tells you.**

EPIRAMAX can help to control your condition. So, you should keep taking the tablets regularly unless advised otherwise by your doctor.

### *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.**

This may increase the chance of you getting an unwanted side effect.

**Ask your doctor or pharmacist if you are not sure what to do.**

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 (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much EPIRAMAX.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too much EPIRAMAX, you may have 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 taking it

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### *Things you must do*

- Drink plenty of water. EPIRAMAX 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 EPIRAMAX.
- Tell your doctor if you become pregnant while taking EPIRAMAX.

### *Things you must not do*

- Do not suddenly stop taking EPIRAMAX without checking with your doctor.
- Do not drink alcohol.
- Do not drive or operate machinery until you know how the medicine affects you.
- Do not use EPIRAMAX 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**

EPIRAMAX 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**

EPIRAMAX may cause drowsiness, dizziness or other symptoms that 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 EPIRAMAX, or if the amount of EPIRAMAX or any other medicine you are taking is increased or decreased.

#### **Effects of food and alcohol**

EPIRAMAX can be taken with or without food.

Do not drink alcohol while taking EPIRAMAX, as 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:**

- nervousness or feeling anxious
- depression
- 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
- peeling of skin, severe rashes, 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 taking it

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### Storage

**Keep EPIRAMAX 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 the tablets in a cool, dry place where the temperature stays below 25°C and protect from moisture.**

**Keep the tablets in their pack until time to take.**

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

**Do not store EPIRAMAX in the bathroom or near a sink.**

**Do not leave EPIRAMAX in the car or on windowsills.**

Heat and dampness can destroy some medicines.

### Disposal

**If your doctor tells you to stop taking EPIRAMAX, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### What it looks like

EPIRAMAX comes in four strengths of tablets:

- EPIRAMAX 25 – white, round, coated tablet debossed with ‘T1’ on one side and plain on the other side
- EPIRAMAX 50 – yellow, round, coated tablet debossed with ‘T1’ over ‘50’ on one side and plain on the other side
- EPIRAMAX 100 – yellow, round, coated tablet with ‘T1’ over ‘100’ on one side and plain on the other side
- EPIRAMAX 200 – pink, round, coated tablet with ‘T1’ over ‘200’ on one side and plain on the other side.

EPIRAMAX is available in blister packs of 60 tablets.

### Ingredients

The active ingredient in EPIRAMAX is topiramate:

- each EPIRAMAX 25 contains 25 mg of topiramate
- each EPIRAMAX 50 contains 50 mg of topiramate
- each EPIRAMAX 100 contains 100 mg of topiramate
- each EPIRAMAX 200 contains 200 mg of topiramate.

The tablets also contain:

- microcrystalline cellulose
- sodium starch glycollate

- pregelatinised maize starch
- lactose
- Aniseed flavour 84165-31
- saccharin sodium
- magnesium stearate
- Opadry AMB OY-B-28920 White (25 mg tablet)
- Opadry AMB 80W62680 Yellow (50 mg tablet)
- Opadry AMB 80W62681 Yellow (100 mg tablet)
- Opadry AMB 80W64830 Pink (200 mg tablet).

The tablets contain sugars as lactose. They also contain saccharin.

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

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## Sponsor

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Australian registration numbers:

### Blister packs

EPIRAMAX 25 - AUST R 135552

EPIRAMAX 50 - AUST R 135592

EPIRAMAX 100 - AUST R 135594

EPIRAMAX 200- AUST R 135596

This leaflet was revised in August 2023.