

## 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 is used for the treatment of various types of epilepsy in adults and children over 2 years of age, and for the prevention of migraines in adults. It prevents seizures and migraines by acting on the nerves and chemicals in the brain.

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 EPIRAMAX

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

**Do not take EPIRAMAX if you have an allergy to:**

- any medicine containing topiramate
- 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 or other parts of the body; skin rash, itching or hives.

**Do not take EPIRAMAX if the expiry date (Exp.) printed on the pack has passed.**

It may not work well if you do.

**Do not take EPIRAMAX if the packaging shows signs of tampering or the tablets do not look quite right.**

**If you are not sure whether you should start taking EPIRAMAX, talk to your doctor.**

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

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you are pregnant or planning to become pregnant.**

EPIRAMAX 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 EPIRAMAX, your doctor can help you decide whether or not to take it during pregnancy.

**Tell your doctor if you are breast feeding or wish to breastfeed.**

EPIRAMAX may appear in breast milk and it is not recommended to breastfeed while taking EPIRAMAX.

**Tell your doctor if you have, or have had, any medical conditions including:**

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

#### *Taking other medicines*

**Tell your doctor or pharmacist 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 EPIRAMAX, or may affect how well it works. These include:

- other medicines for epilepsy, such as valproic acid, phenytoin, carbamazepine
- digoxin, a medicine used to treat some heart disease
- oral contraceptives (the pill)
- metformin, pioglitazone, glibenclamide, medicines for diabetes
- acetazolamide, medicine used to treat glaucoma
- lithium, risperidone and venlafaxine, medicines for mood disorders
- hydrochlorothiazide, medicine used to treat swelling or high blood pressure
- propranolol and diltiazem, medicines used to treat hypertension or prevent angina
- any medicine that slows your reactions eg medicines to help you sleep or relieve pain, anti-depressants, tranquillisers or

antihistamines that 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 EPIRAMAX.

**If you have not told your doctor about any of the above, tell them before you start taking EPIRAMAX.**

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## How to take EPIRAMAX

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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)** - 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 EPIRAMAX*

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

### *When to take EPIRAMAX*

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 EPIRAMAX*

**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.

**If you 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 (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 EPIRAMAX

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### *Things you must do*

**Tell all doctors, dentists and pharmacists who treat you that you are taking EPIRAMAX.**

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking EPIRAMAX.**

**Make sure you drink enough water during exercise and in hot weather when you are taking EPIRAMAX.**

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

**Tell your doctor if you become pregnant while taking EPIRAMAX.**

**Take EPIRAMAX exactly as your doctor has prescribed.**

Otherwise, you may not get the benefits from treatment. Also, your doctor may think that it is not working and change your treatment unnecessarily.

### ***Things you must not do***

**Do not stop taking EPIRAMAX or change the dosage, unless advised by your doctor.**

**Do not use EPIRAMAX to treat any other medical complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

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

**Do not drink alcohol at the same time with EPIRAMAX.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how EPIRAMAX affects you.**

EPIRAMAX may cause drowsiness, dizziness or other symptoms that could affect your ability to drive or operate machinery in some people.

Make sure you know how you react to EPIRAMAX before you drive, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed.

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.

**Be careful with alcohol.**

Avoid drinking 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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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking EPIRAMAX.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention 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 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 have any of the following as you may need medical attention:**

- difficulty with concentration or attention; confusion
- difficulty with memory and/or thinking
- depression, mood problems, abnormal thoughts, thoughts of harming yourself
- agitation or unusual nervousness
- reduced sweating or overheating (mainly in children) - feeling flushed or overheated more than usual, particularly during exercise or hot weather.
- co-ordination problems, tremor or slow reaction
- speech or language problems

- effects on eyes or vision (eg double vision)
- symptoms of frequent infections like fever, severe chills, sore throat or mouth ulcers
- sudden severe back or side pain, difficult or painful to pass urine.

**Tell your doctor immediately if you experience any of the following:**

- **Suicidal thoughts**
- **Suicidal attempts**

**Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.**

**If you notice any of the following while taking EPIRAMAX, stop taking it and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing (allergic reactions)
- 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 (eg 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 serious side effects. You may need urgent medical attention or hospitalisation.

**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.**

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## **After taking EPIRAMAX**

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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 window sills.**

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 with 'TI' on one side and 'D' on the other side
- EPIRAMAX 50 – yellow, round, coated tablet with 'TI' over '50' on one side and 'D' on the other side
- EPIRAMAX 100 – yellow, round, coated tablet with 'TI' over '100' on one side and 'D' on the other side
- EPIRAMAX 200 – pink, round, coated tablet with 'TI' over '200' on one side and 'D' on the other side.

EPIRAMAX is available in blister packs and bottles 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
- anhydrous lactose
- Anis (aniseed flavour)
- 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 do not contain gluten, sucrose, tartrazine or any other azo dyes.

### ***Sponsor***

Sigma Pharmaceuticals (Australia) Pty Ltd  
96 Merrindale Drive  
Croydon Vic 3136  
Tel: 03 - 9839 2800

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

Date of preparation  
September 2009.