

# Arrow - Topiramate

## Topiramate

15 mg, 25 mg and 50 mg Capsules

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

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## What is in this leaflet

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This leaflet answers some common questions about ARROW - TOPIRAMATE Capsules and 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 ARROW – TOPIRAMATE 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.

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## What ARROW - TOPIRAMATE is used for

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TOPIRAMATE, the active ingredient in ARROW - TOPIRAMATE Capsules and 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 ARROW – TOPIRAMATE on its own, or in addition to another medicine for controlling your seizures or migraines.

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

There is no evidence that ARROW – TOPIRAMATE is addictive.

ARROW – TOPIRAMATE is available only with a doctor's prescription.

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## Before you take ARROW - TOPIRAMATE

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### *When you must not take it*

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

It may not work well if you do.

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

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

**Certain people must use ARROW - TOPIRAMATE 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.**

There is no experience with the use of ARROW - TOPIRAMATE during pregnancy and its safety has not been verified. If your doctor thinks it is necessary for you to take it, he or she will discuss the benefits and risks involved.

**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 ARROW - TOPIRAMATE.

**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 ARROW - TOPIRAMATE, 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 ARROW - TOPIRAMATE.

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

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## **How to take ARROW - TOPIRAMATE**

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**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.

### ***How to take it***

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

For people who have difficulty in swallowing medicines, ARROW - TOPIRAMATE Capsules can be opened to sprinkle all of the contents onto a teaspoon of soft food that does not require chewing. This mixture should then be swallowed immediately without chewing. It should not be stored for future use.

### ***When to take it***

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

**Take ARROW - TOPIRAMATE 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 ARROW - TOPIRAMATE 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 ARROW – TOPIRAMATE Capsules or 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 ARROW - TOPIRAMATE, 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 taking ARROW - TOPIRAMATE**

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***Things you must do***

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

**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 ARROW - TOPIRAMATE, 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 ARROW - TOPIRAMATE to treat any other conditions unless your doctor tells you to.**

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

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

**Do not give ARROW - TOPIRAMATE 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 ARROW - TOPIRAMATE until you know how it affects you.**

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

**Avoid alcohol while taking ARROW - TOPIRAMATE.**

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 ARROW – TOPIRAMATE.**

Like other medicines, ARROW - TOPIRAMATE 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 ARROW - TOPIRAMATE, 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.

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## **After using ARROW - TOPIRAMATE**

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### ***Storage***

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

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

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

**Do not store ARROW - TOPIRAMATE 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 ARROW - TOPIRAMATE, or your medicine has passed its 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 ARROW - TOPIRAMATE looks like***

**Capsules**

ARROW - TOPIRAMATE Capsules are hard gelatin capsules with white opaque cap and body, containing white to off-white round pellets. Three strengths are available and packed in opaque bottles of 60 capsules:

15 mg – marked with '>' over 'Ti' on the cap and '15' on the body  
25 mg – marked with '>' over 'Ti' on the cap and '25' on the body  
50 mg – marked with '>' over 'Ti' on the cap and '50' on the body.

### **Tablets**

ARROW - TOPIRAMATE Tablets are available in four strengths, supplied in both opaque bottles and foil blister packs of 60 tablets:

25 mg – white, round, coated tablet with 'Ti' on one side and '>' on the other side  
50 mg – yellow, round, coated tablet with 'Ti' over '50' on one side and '>' on the other side  
100 mg – yellow, round, coated tablet with 'Ti' over '100' on one side and '>' on the other side  
200 mg – pink, round, coated tablet with 'Ti' over '200' on one side and '>' on the other side.

### **Ingredients**

Each ARROW - TOPIRAMATE Capsule contains:

- 15 mg, 25 mg or 50 mg as the active ingredient
- capsule shell that consists of gelatin and titanium dioxide, and is imprinted with black ink
- excipients including povidone, Opadry II 85F18378 White, aniseed flavour, saccharin sodium and magnesium stearate.

Each ARROW - TOPIRAMATE Tablet contains:

- 25 mg, 50 mg, 100 mg or 200 mg as the active ingredient
- excipients including microcrystalline cellulose, sodium starch glycollate, pregelatinised maize starch, lactose, aniseed flavour and saccharin sodium
- colouring agent Opadry AMB OY-B-28920 White for 25 mg Tablets, Opadry AMB 80W62680 Yellow for 50 mg Tablets, Opadry AMB 80W62681 Yellow for 100 mg Tablets, and Opadry AMB 80W64830 Pink for 200 mg Tablets.

### **Supplier**

ARROW - TOPIRAMATE is distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Limited  
33a Normanby Road, Mt. Eden  
Auckland, New Zealand.

### **Date of preparation**

24 February 2010