

NOUMED TOPIRAMATE

topiramate tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NOUMED TOPIRAMATE.

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 risks of taking this medicine against the benefits it is expected to have for you or your child.

If your child is being treated with NOUMED TOPIRAMATE, follow the same instructions in this leaflet as you would as a patient.

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 NOUMED TOPIRAMATE is used for

NOUMED TOPIRAMATE tablets contain the active ingredient topiramate.

Topiramate belongs to a group of medicines called anti-epileptics. These drugs prevent seizures and migraines by acting on the nerves and chemicals in the brain.

NOUMED TOPIRAMATE is used to treat various types of epilepsy in adults and children over 2 years of age, and to prevent migraines in adults.

This medicine is available only with a doctor's prescription.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you take it

When you must not take it

Do not take this medicine if you have an allergy to topiramate, other similar medicines, or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty in breathing; swelling of the face, lips tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you take it after the expiry date has passed, it may not work as well.

If it has expired or is damaged, return the pack to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, 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 have or have ever had any of the following medical conditions:

- a personality disorder or mental illness
- kidney stones, kidney disease or a family history of kidney stones
- liver disease
- eye problem or high pressure in the eye
- a history of metabolic acidosis (too much acidity in the blood, which may cause increased rates of breathing).

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

Using topiramate during pregnancy may lead to birth defects including cleft lip/palate in babies. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take this medicine, your doctor can discuss with you the potential risks.

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

Topiramate may appear in breast milk and it is not recommended to breastfeed while taking this medicine.

If you have not told your doctor about any of the above, tell him/her before you start taking NOUMED TOPIRAMATE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a

pharmacy, supermarket or health food shop.

Some medicines and NOUMED TOPIRAMATE may interfere with each other. In particular, tell your doctor or pharmacist if you are taking:

- other medicines for epilepsy, such as phenytoin, carbamazepine, valproic acid or flunarizine
- digoxin (for treat heart disease)
- oral contraceptives (the pill)
- metformin, pioglitazone, glibenclamide (for diabetes)
- lithium or risperidone (for bipolar disorder and schizophrenia)
- hydrochlorothiazide (for swelling or high blood pressure)
- warfarin or other vitamin-K antagonist anticoagulants (to prevent blood clotting)
- amitriptyline (for depression)
- haloperidol (for psychoses)
- propranolol (for high blood pressure, heart conditions, migraine headaches, tumours)
- diltiazem (for hypertension and angina)
- any medicine which slows your reactions. 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 NOUMED TOPIRAMATE, or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

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

How to take NOUMED TOPIRAMATE

How much to take

The amount of NOUMED TOPIRAMATE you or your child will take is determined by your doctor.

Your doctor will start with a low dose and slowly increase the dose to the lowest amount needed to control your condition. The changes in dose are made at intervals of one week or longer to help you cope with its effects.

The doses shown below are the recommended doses.

Epilepsy

The dose depends on whether NOUMED TOPIRAMATE is taken alone (monotherapy), or used with another medication (add-on therapy).

In adults, treatment starts at 25 mg to 50 mg per day then increased by 25 to 100 mg until a suitable effective dose of 100 to 400 mg is reached.

In children 2 years or older, treatment starts at 25 mg or less per day depending on the child's body weight then gradually increased to 3 to 9 mg per day for every kg weight.

Migraine (adults only)

Treatment starts at 25 mg per day then increased by 25 mg in intervals of one week or longer until an effective dose of 50 to 200 mg per day is reached.

Ask your doctor or pharmacist if you are unsure of the correct dose for you or do not understand the instructions.

They will tell you exactly how much to take.

Follow all directions they give you carefully.

If you take the wrong dose, NOUMED TOPIRAMATE may not work as well and your condition may not be adequately controlled.

How to take it

Swallow the tablets whole with plenty of water.

You can take the tablets with or without food.

When to take it

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

Take your medicine at about the same times each day.

Taking it at the same times each day will have the best effect. It will also help you remember when to take it.

How long to take it

You should continue taking NOUMED 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

Take your dose as soon as you remember, and 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 that you missed.

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

If you have missed more than one dose, or are not sure what to do, ask your doctor pharmacist.

If you have trouble remembering 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 (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that

you or anyone else has taken too much NOUMED TOPIRAMATE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep this telephone number handy.

If you take too much NOUMED TOPIRAMATE, you may experience headache, dizziness, lightheadedness, 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 it

Things you must do

Always follow your doctor's instructions carefully.

Tell your doctor if you become pregnant while taking NOUMED TOPIRAMATE.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking NOUMED TOPIRAMATE.

Drink plenty of water.

Topiramate has been known to cause kidney stones. Drinking plenty of water may help prevent this.

Things you must not do

Do not stop taking NOUMED TOPIRAMATE without checking with your doctor.

Do not take NOUMED TOPIRAMATE to treat any other complaints unless your doctor tells you to.

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

Do not drink alcohol.

Things to be careful of

Changes to your medication

Even if you are seizure-free or your seizures are well controlled, check with your doctor before lowering your dose, stopping or replacing with another medicine.

Your doctor will monitor your condition and will ask you to implement any changes gradually.

Effects on thoughts and behaviour

Medicines used to treat epilepsy can increase the risk of suicidal thoughts and behaviour.

Tell your doctor immediately if you have any feelings of deep sadness and unworthiness (depression), a worsening of these feelings, any unusual changes in your mood or the emergence of suicidal thoughts, behaviour or thoughts of self-harm.

Sweating and fever

Topiramate may affect your body's ability to cope with temperature changes by not sweating as much or causing fever.

Call your doctor immediately if you or your child has a high fever, a fever that does not go away, or do not sweat as usual.

Some people may need to be admitted to hospital.

Driving and operating machinery

NOUMED TOPIRAMATE 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.

Take special care when you first start taking NOUMED TOPIRAMATE or the dose you are taking is changing.

Effects of alcohol

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 NOUMED TOPIRAMATE.

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 the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they 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
- stomach pain or discomfort
- pain, buzzing or ringing in ears, or deafness

These are the more common side effects of NOUMED TOPIRAMATE.

Tell your doctor as soon as possible if you notice any of the following:

- depression
- nervousness or feeling anxious
- changes in mood, such as aggressiveness, agitation or anger
- disturbance in attention
- difficulties with memory, or slowing of your thinking process
- abnormal behaviour
- difficulty in speaking or expressing yourself
- balance or co-ordination problems
- excessive hair loss or thinning
- unusually frequent urination

- lessened feeling or sensitivity, especially in the skin
- fever or high temperature
- lack of sweating; overheating
- loss or changes to sense of taste
- are unusually weak, tired, drowsy, irritable or lack energy
- difficulty breathing
- fast or irregular heartbeat, or tightening of the chest
- thoughts of harming yourself or suicide
- kidney stones, or pain when passing urine
- sudden changes in your eyesight (such as blurred, double or loss of vision), or rapid uncontrollable movements of the eyes
- eye pain or increased pressure in eye
- unexplained bleeding, more frequent bleeding
- severe blisters and bleeding in the lips, eyes, mouth, nose, genitals.

These are side effects of NOUMED TOPIRAMATE. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking it

Storage

Keep your medicine in the original container until it is time to take them.

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

Keep your medicine in a cool, dry place, protected from light, where the temperature stays below 25°C.

Do not store it, or any other medicine, in the bathroom or near a

sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine 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.

Disposal

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

Product description

What it looks like

NOUMED TOPIRAMATE is available in 4 strengths that are supplied in bottles or blister packs of 60 tablets each*.

25 mg: white, round, film-coated tablets; plain on both sides.

50 mg: yellow, round, film-coated tablets; plain on both sides.

100 mg: white, round, film-coated tablets; plain on both sides.

200 mg: white, round, film-coated tablets; plain on both sides.

**not all presentations may be available.*

Ingredients

Active ingredient

NOUMED TOPIRAMATE tablets contain either 25 mg, 50 mg, 100 mg or 200 mg of topiramate.

Inactive ingredients

- lactose monohydrate
- pregelatinized maize starch
- microcrystalline cellulose
- sodium starch glycollate
- magnesium stearate
- macrogol 400
- polysorbate 80

- hypromellose
- titanium dioxide
- iron oxide yellow (50 mg and 200 mg tablets only)

NOUMED TOPIRAMATE does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Avallon Pharmaceuticals Pty Ltd
Level 5, 7 Eden Park Drive
Macquarie Park NSW 2113
Telephone 1800 930 999

Australian registration numbers

25 mg: AUST R 284339 (blister packs), 284343 (bottles)
50 mg: AUST R 284340 (blister packs), 284344 (bottles)
100 mg: AUST R 284341 (blister packs), 284345 (bottles)
200 mg: AUST R 284342 (blister packs), 284346 (bottles)

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