

i **PACKAGE LEAFLET:**
Information for the patient

TOPIRAMAT

Film – coated tablets – 25 mg
(Topiramate)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT TOPIRAMAT IS AND WHAT IT IS USED FOR

- Topiramate is used to treat some types of seizure:
 - partial seizures (seizures affecting only part of the brain) and/or;
 - generalised tonic-clonic seizures (these are sometimes called Grand Mal seizures and affect the whole brain; they have a 'tonic phase' when the patient falls unconscious and the muscles suddenly tense up and a 'clonic phase' when the patient's muscles contract and relax rapidly, causing convulsions).
- Topiramate is used on its own to treat epilepsy in adults and adolescents over 12 years of age.
- Topiramate is used with other medicines to treat epilepsy in adults, adolescents and children of 6-12 years of age.
- Topiramate is also used for the prophylaxis of migraine:
 - to prevent frequently recurring migraine headaches in adults when earlier treatment with other medicines was not effective. It is not intended to treat an individual migraine attack.

2. BEFORE YOU TAKE TOPIRAMAT

Do not take Topiramate:

- if you are hypersensitive (allergic) to topiramate or to any of the other ingredients of this medicine;
- for the prevention of migraine if you are pregnant or of child-bearing age and you are not using an effective method of contraception, increasing the risk of being pregnant.

Take special care with Topiramate

Ask your doctor before you take Topiramate if you:

- or a family member have or have had kidney stones (Topiramate can increase the risk of kidney stones; your doctor may ask you to drink more water while taking Topiramate);
- are having haemodialysis; in this case your dose may need to be adjusted;
- have problems with your kidneys or liver; in this case your doctor may want to prescribe a lower dose;
- have had thoughts of harming or killing yourself and if at any point you have these thoughts, immediately contact your doctor;
- have a severe respiratory condition such as asthma or chronic obstructive pulmonary disease;
- have status epilepticus (when the brain is in persistent seizure);
- have diarrhea;
- have recently had an operation;
- have a fatty and protein rich diet;
- have ever had porphyria;
- have decrease of sweating, especially in children (this can cause your body temperature to rise during exercise and exposure to warm environments; therefore, it is important to drink plenty of water during treatment, especially if you are doing exercise or if the weather is hot; this will reduce the risk of heat-related side effects, like headache and nausea).

You may experience significant and continuing weight loss while taking this medicine. You should talk to your doctor and you should eat more food.

Eye Problems

Contact your doctor straight away if you suddenly get blurred vision, painful or red eyes. This could be a sign of raised pressure within the eye (glaucoma). It can happen to adults and children, usually during the first month of treatment.

If you develop any other problems with your eyes, contact an eye specialist or your doctor straight away.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by topiramate.

Do not forget to inform your doctor for the treatment with topiramate if you receive any other medicine during treatment.

In particular tell your doctor if you are taking the following medicines:

- other antiepileptic medicines such as phenytoin or carbamazepine;
- digoxin for heart failure;
- hydrochlorothiazide or triamterene (water tablets);
- medicines for diabetes such as metformin, pioglitazone or glibenclamide;
- medicines for depression, such as amitriptyline, imipramine, moclobemide;
- diazepam (a sedative);
- proguanil (to treat malaria);
- omeprazole (for ulcers and other conditions caused by too much stomach acid);
- acetazolamide;
- high doses of vitamin C;
- haloperidol (for mental illness);
- propranolol (for high blood pressure);
- any medicines that make you sleepy or less alert (including tranquillisers, anti-depressants and sleeping pills);
- oral contraceptives. Your contraception may be less effective. You should consult your doctor if your menstrual bleeding patterns change.

Taking Topiramate with food and drinks

- You can take the tablets with or without food.
- It is important to drink plenty of water when taking topiramate, especially if you exercise or when it is hot.
- You should be careful how much alcohol you drink while taking Topiramate because the combination of alcohol with this medicine might make you feel less alert than usual.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you might be pregnant or if you intend to become pregnant. Your doctor will discuss with you if you should continue to take Topiramate.

- Topiramate may cause an increased risk of birth defects in your developing baby.
- Tell your doctor if you are breast-feeding. Your doctor may ask you to stop breast-feeding as Topiramate may reach your baby through your milk.
- You must not take Topiramate if you are a woman of child-bearing age and you are not using an effective contraception.
- You must not take Topiramate to prevent migraine attacks if you are pregnant.

Driving and using machines

Topiramate may cause drowsiness, dizziness, blurred vision and other symptoms associated with the use of topiramate. If any of these things happens to you, do not drive or use machines.

Important information about some of the ingredients of Topiramate

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE TOPIRAMAT

Always take Topiramate exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of topiramate are too strong or too weak, talk to your doctor or pharmacist.

Usually the daily dose is taken as two separate single doses. Do not break or chew the tablets. Swallow the tablets whole with plenty of water. You can take the tablets with or without food.

Treatment of epilepsy

Treatment with topiramate should start with a low dose, and the dose should be increased gradually.

- *Treatment of epilepsy only with topiramate in adults and adolescents of more than 12 years of age:* the usual starting dose is 25 mg topiramate as a single evening dose for one week. This dose may be increased by your doctor at weekly or fortnightly intervals by either 25 mg or 50 mg until your seizures are controlled. The usual maintenance dose is 100 mg per day (50 mg in the morning and 50 mg in the evening). The maximum daily recommended dose is 400 mg.
- *Treatment of epilepsy with topiramate plus other antiepileptic drugs:*
- *Adults and adolescents of more than 12 years of age:* the usual starting dose is 25 mg topiramate as a single evening dose for one week. This dose may be increased by your doctor at weekly or fortnightly intervals by either 25 mg or 50 mg until your seizures are controlled. The usual dose is 200 mg to 400 mg topiramate per day, given in two doses.
- *Children aged 6 to 12 years:* your doctor will work out the dose needed. This will depend on the weight of your child. The dose may be increased slowly at weekly or fortnightly intervals until your child's seizures are controlled.

Prophylaxis of migraine:

- It is important that you follow your doctor's instructions carefully to help reduce the chance of getting a migraine headache.
- Do not use topiramate in children and adolescents to prevent migraine headaches.

The usual starting dose for adults is 25 mg topiramate as a single evening dose for one week. The usual maintenance dose is 100 mg per day in two divided doses of 50 mg in the morning and 50 mg at night.

The use of topiramate in people with liver or kidney problems:

- If you have liver or kidney disease your doctor may tell you to take a lower dose of topiramate than those described above.
- If you have to undergo haemodialysis, your doctor may tell you to follow a different dosing schedule than those described above.

If you are not sure how many tablets to take or when to take them, ask your doctor.

If you take more Topiramate than you should

If you take more Topiramate than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures. Signs of an overdose include: headache, somnolence, impaired speech, blurred vision, diplopia, impaired mental activity, lethargy, abnormal coordination, hypotension, abdominal pain, agitation, dizziness, depression and convulsions. Overdose with topiramate may result in serious metabolic acidosis and hypokalaemia.

If you forget to take Topiramate

If you forget to take one dose (or more than one dose), take the next dose in its usual time. Do not take a double dose (or higher) to make up a forgotten dose(s).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking Topiramate

Do not suddenly stop taking this medicine without first checking with your doctor. If you have to stop taking this medicine, you must first reduce the dose gradually, over several weeks, avoiding in this way the emergence of epilepsy seizures due to the instant interruptions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Topiramate can cause side effects, although not everybody gets them. Sometimes they are serious, most of the times not. Do not be alarmed by this list of possible side effects. You may not get any of them. Stop taking this drug and consult your doctor if you notice any of the following serious side effects:

- swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice itching of the skin or a nettle rash. This could mean you are having an allergic reaction;
- blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and fever. These could be signs of a serious illness called Stevens-Johnson syndrome;
- fits or convulsions;
- thoughts of harming or killing yourself;
- yellowing of your skin or eyes or changes in the way your liver is working shown by a blood test. These may be signs of liver problems or liver failure;
- any eye problems, including double vision, blurred vision, short-sightedness or eye pain. These may be signs of raised pressure within the eye (angle closure glaucoma).

Very common side effects (affect more than 1 in 10 people):

- feeling dizzy, tired or sleepy;
- numbness or tingling of your skin (paraesthesia);
- feeling sick (nausea), diarrhoea, stomach pain or indigestion;
- weight loss, loss of appetite, dry mouth or changes in the way things taste;
- feeling anxious or nervous, having mood swings or depression;
- language and speech problems;
- co-ordination problems.

Common side effects (affect less than 1 in 10 people):

- feeling weak;
- pain in your bones;
- difficulty breathing, slow heart rate, nausea and feeling confused. This could be due to too much acid in your blood (metabolic acidosis);
- feeling tired, faint, dizzy or having pale skin. These could be symptoms of anaemia;
- getting infections more often than usual or bruising more easily than usual. These could be signs of a blood problem such as leucopenia, neutropenia or thrombocytopenia;
- lack of feeling or emotion (apathy) or feeling unusually happy (euphoria);
- finding it harder than usual to control your emotions;
- feeling restless or more aggressive than usual;
- reduced sex drive;
- constipation, stomach pain;
- hair loss (alopecia);
- urinary incontinence;

- nose bleeds;
- rash or dark red spots under the skin;
- blood in your urine or pain in the lower back or genital area. These may be signs that you have kidney stones;
- difficulty in walking;
- menstrual problems.

Uncommon side effects (affect less than 1 in 100 people):

- hallucinations;
- changes in your behaviour or thinking such as feeling that you can't trust anyone, avoiding situations where you need to mix with other people, having outbursts of anger, compulsive behavior;
- breathing problems such as shortness of breath or difficulty breathing;
- diarrhoea, being sick (vomiting), dry mouth;
- red, sore or inflamed skin around hair roots; this could be due to an infection called folliculitis;
- itchy skin;
- unusually reduced or slow body movements;
- feeling dazed, less alert or aware of your surroundings than usual.

Rare side effects (affect less than 1 in 1,000 people):

- sweating less than usual, particularly during exercise or hot weather. This is more likely to happen in children.

Side effects in children (6 years of age or older):

In clinical studies with children 6 years of age or older, the following additional effects were observed: abnormally increased muscular movements (hyperkinesias), abnormal behaviour, increased salivation.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TOPIRAMAT

Keep out of the reach and sight of children. Do not use this medicine after the expiry date which is stated on the package. Do not store above 25°C.

6. OTHER INFORMATION

What Topiramate – Film-coated tablet 25 mg contains?

Each film-coated tablet contains 25 mg topiramate.

The other ingredients are:


Tablet core: lactose monohydrate and corn starch, microcrystalline cellulose, talc, magnesium stearate, crospovidone.

Film-coating: Opadry II white.

Contents of the pack:

Carton box with 30 tablets.


Explanatory of the illustration icons on the packaging:

 According to medical prescription.

 Content.  Warning.

 Tablet shape.

Marketing Authorisation Holder (MAH) and manufacturer:

 **PROFARMA Sh.a.**
Rruga "Myslym Keta"
Tel./ Fax: 00 355 4 23 62 800
Tirana - ALBANIA

This leaflet was last revised in October 2014.