

## Package leaflet: Information for the user

**Topiramate Pharmathen 25 mg film-coated tablets**  
**Topiramate Pharmathen 50 mg film-coated tablets**  
**Topiramate Pharmathen 100 mg film-coated tablets**  
**Topiramate Pharmathen 200 mg film-coated tablets**  
Topiramate

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- 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 you get any of effects talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

### **What is in this leaflet:**

1. What Topiramate Pharmathen is and what it is used for
2. What you need to know before you take Topiramate Pharmathen
3. How to take Topiramate Pharmathen
4. Possible side effects
5. How to store Topiramate Pharmathen
6. Contents of the pack and other information

### **1. What Topiramate Pharmathen is and what it is used for**

Topiramate Pharmathen belongs to a group of medicines called “antiepileptic medicines”. It is used:

- alone to treat seizures in adults and children over age 6
- with other medicines to treat seizures in adults and children over age 2
- to prevent migraine headaches in adults

### **2. What you need to know before you take Topiramate Pharmathen**

#### **Do not take Topiramate Pharmathen**

- if you are allergic to topiramate or any of the other ingredients of this medicine (listed in section 6).
- for migraine prevention if you are pregnant or you are able to become pregnant but you are not using an effective contraception (see section ‘pregnancy and breast feeding’).

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Topiramate Pharmathen.

**Warnings and precautions** Check with your doctor or pharmacist before taking Topiramate Pharmathen if you:

- have kidney problems, especially kidney stones, or are getting kidney dialysis
- have a history of blood and body fluid abnormality (metabolic acidosis)
- have liver problems
- have eye problems, especially glaucoma
- have a growth problem
- are on a high fat diet (ketogenic diet)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Topiramate Pharmathen.

It is important that you do not stop taking your medicine without first consulting your doctor.

You should also talk to your doctor before taking any medicine containing topiramate that is given to you as an alternative to Topiramate Pharmathen.

You may lose weight if you use Topiramate Pharmathen so your weight should be checked regularly when using this medicine. If you are losing too much weight or a child using this medicine is not gaining enough weight, you should consult your doctor.

A small number of people being treated with anti-epileptics such as Topiramate Pharmathen have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

### **Other medicines and Topiramate Pharmathen**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, vitamins and herbal medicines. Topiramate Pharmathen and certain other medicines can affect each other. Sometimes the dose of some of your other medicines or Topiramate Pharmathen will have to be adjusted.

Especially, tell your doctor or pharmacist if you are taking:

- other medicines that impair or decrease your thinking, concentration, or muscle coordination (e.g. central nervous system depressant medicines such as muscle relaxants and sedatives).
- birth control pills. Topiramate Pharmathen may make your birth control pills less effective. Tell your doctor if your menstrual bleeding changes while you are taking birth control pills and Topiramate Pharmathen.

Keep a list of all the medicines you take. Show this list to your doctor and pharmacist before you start a new medicine.

Other medicines you should discuss with your doctor or pharmacist include other antiepileptic medicines, risperidone, lithium, hydrochlorothiazide, metformin, pioglitazone, glyburide, amitriptyline, propranolol, diltiazem, venlafaxine, flunarazine

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Topiramate Pharmathen.

### **Taking Topiramate Pharmathen with food ,drink and alcohol**

You can take Topiramate Pharmathen with or without food. Drink plenty of fluids during the day to prevent kidney stones while taking Topiramate Pharmathen. You should avoid drinking alcohol when taking Topiramate Pharmathen.

### **Pregnancy and breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide if you can take Topiramate Pharmathen. As with other antiepilepsy medicines, there is a risk of harm to the unborn child if Topiramate Pharmathen is used during pregnancy. Make sure you are very clear about the risks and the benefits of using Topiramate Pharmathen for epilepsy during pregnancy.

You should not take Topiramate Pharmathen for migraine prevention if you are pregnant or you are able to become pregnant and you are not using effective contraception.

Mothers who breastfeed while taking Topiramate Pharmathen must tell the doctor as soon as possible if the baby experiences anything unusual.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Dizziness, tiredness, and vision problems may occur during treatment with Topiramate Pharmathen. Do not drive or use any tools or machines without talking to your doctor first.

### **Topiramate Pharmathen contains lactose and azo-dye Sunset Yellow (E110)**

Topiramate Pharmathen (25 mg, 50 mg and 200 mg) 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.

Topiramate Pharmathen (only 100 mg) contains the azo-dye Sunset Yellow (E110). May cause allergic reactions.

## **3. HOW TO TAKE How to take Topiramate Pharmathen**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Take Topiramate Pharmathen exactly as prescribed. Your doctor will usually start you on a low dose of Topiramate Pharmathen and slowly increase your dose until the best dose is found for you.
- Topiramate Pharmathen tablets are to be swallowed whole. Avoid chewing the tablets as they may leave a bitter taste.
- Topiramate Pharmathen can be taken before, during, or after a meal. Drink plenty of fluids during the day to prevent kidney stones while taking Topiramate Pharmathen.

**If you take more Topiramate Pharmathen than you should**

- See a doctor right away. Take the medicine pack with you.
- You may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heart beats or fits.

Overdose can happen if you are taking other medicines together with Topiramate Pharmathen.

**If you forget to take Topiramate Pharmathen**

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

**If you stop taking Topiramate Pharmathen**

Do not stop taking this medicine unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop this medication, your dose may be decreased gradually over a few days.

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:

very common (may affect more than 1 in 10 people)

common (may affect up to 1 in 10-people)

uncommon (may affect up to 1 in 100 people)

rare (may affect up to 1 in 1000 people)

very rare ( may affect up to 1 in 10,000 people)

not known (frequency cannot be estimated from the available data).

**Very common side effects include:**

- Weight loss
- Tingling in the arms and legs
- Drowsiness or sleepiness
- Dizziness
- Diarrhoea
- Nausea
- Stuffy, runny nose and sore throat
- Tiredness
- Depression

**Common side effects include:**

- Changes in mood or behaviour, including anger, nervousness, sadness
- Weight gain
- Decrease or loss of appetite
- Reduced number of red blood cells
- Changes in thinking and alertness, including confusion, problems with concentration, memory or slowness in thinking
- Slurred speech
- Clumsiness, or problems with walking
- Involuntary shaking in the arms, hands or legs
- Reduced sense of touch or sensation
- Involuntary movement of the eyes
- Distorted sense of taste
- Visual disturbance, blurred vision, double vision
- Ringing sound in the ears
- Ear pain
- Shortness of breath
- Nose bleeds
- Vomiting
- Constipation
- Stomach pain
- Indigestion
- Dry mouth
- Tingling or numbness of the mouth
- Kidney stones
- Frequent urination
- Painful urination
- Hair loss
- Skin rash and/or itchy skin.
- Joint pain
- Muscle spasms, muscle twitching or muscle weakness
- Chest pain
- Fever
- Loss of strength
- General feeling of feeling unwell
- Allergic reaction

**Uncommon side effects include:**

- Crystals in the urine
- Abnormal blood counts, including reduced white blood cell count or platelet count, or increased eosinophils
- Irregular heartbeat or slowness of the heart beat
- Swollen glands in the neck armpit or groin
- Increase in seizures
- Problems with verbal communication
- Drooling
- Restlessness or increased mental and physical activity
- Loss of consciousness
- Fainting
- Slow or diminished movements
- Disturbed or poor quality sleep
- Impaired or distorted sense of smell
- Problems with handwriting
- Feeling of movement under the skin
- Eye problems including dry eyes, light sensitivity, involuntary twitching, tearing and decreased vision
- Decreased or loss of hearing.
- Hoarseness of the voice
- Inflammation of the pancreas
- Gas
- Heartburn
- Loss of sensitivity to touch in the mouth
- Bleeding gums
- Fullness or bloating
- Painful or burning sensations in the mouth
- Breath odour
- Leakage of urine and/or stools
- Urgent desire to urinate
- Pain in the kidney area and/or bladder caused by kidney stones
- **Decrease or loss of sweating**
- Skin discolouration
- Localized swelling in the skin
- Swelling of the face.
- Swelling of the joints.
- Musculoskeletal stiffness
- **Increased** acid levels in the blood
- Low potassium levels in the blood
- Increased appetite
- Increased thirst and drinking abnormally large amounts of fluid
- Low blood pressure or decrease in blood pressure that occurs when you stand up
- Hot flushing
- Flu like illness
- Cold extremities (e.g. hands and face)
- Problems with learning
- Disturbances in sexual function (erectile dysfunction, loss of libido)
- Hallucinations
- Decreased verbal communication

**Rare side effects include:**

- Excessive skin sensitivity
- Impaired sense of smell
- **Glaucoma which is a blockage of fluid in the eye causing increased pressure in the eye, pain and decreased vision**
- Renal tubular acidosis
- Severe skin reaction, including Stevens-Johnson syndrome, a life threatening skin condition in which the upper layer of the skin separates from the lower, and erythema multiforme, a condition of raised red spots that can blister
- Odour
- Swelling in the tissues around the eye
- Raynaud's syndrome. A disorder affecting the blood vessels, in the fingers, toes, ears and causing
- Tissue calcification (calcinosis).
- Liver inflammation (hepatitis), liver failure

**Side effects of unknown frequency:**

- Maculopathy is a disease of the macula, the small spot in the retina where vision is keenest. You should call your doctor if you notice a change or decrease in your vision
- Swelling of the conjunctive of the eye
- Toxic epidermal necrolysis which is a more severe form of Stevens-Johnson syndrome (see uncommon side effects).

If you get any side effects talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

**5. How to store Topiramate Pharmathen**

Keep this medicine out of the sight and reach of children.

Do not use Topiramate Pharmathen after the expiry date which is on the label. The expiry date refers to the last day of that month.

*Blister 25 mg, 50 mg and 200 mg:* No special storage conditions.

*Blister 100 mg:* Do not store above 30° C.

*Multidose container:* No special storage conditions.

Store in the original package in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Contents of the pack and other information**

## What Topiramate Pharmathen contains

The active substance is topiramate:

*25 mg film-coated tablets:*

One film-coated tablet contains 25 mg topiramate.

*50 mg film-coated tablets:*

One film-coated tablet contains 50 mg topiramate.

*100 mg film-coated tablets:*

One film-coated tablet contains 100 mg topiramate.

*200 mg film-coated tablets:*

One film-coated tablet contains 200 mg topiramate.

The other ingredients are:

*Tablet core:* Microcrystalline cellulose, mannitol, sodium starch glycolate (type A), pregelatinised starch, crospovidone, povidone, magnesium stearate, carnauba wax.

*Coating:* Hypromellose, lactose monohydrate (only 25 mg, 50 mg and 200 mg), macrogol 4000 (only 25 mg, 50 mg and 200 mg), talc (only 50 mg), propylene glycol (only 50 mg and 100 mg), titanium dioxide (E 171), quinoline yellow (E104) (only 50 mg), sunset yellow (E110) (only 100 mg), red and yellow ferric oxide (E 172) (only 200 mg), talc (only 100mg).

## What Topiramate Pharmathen looks like and contents of the pack:

*25 mg:* white, round, biconvex film-coated tablets

*50 mg:* yellow, round, biconvex film-coated tablets

*100 mg:* orange, oblong, biconvex film-coated tablets

*200 mg:* pink, oblong, biconvex film-coated tablets

Pack sizes: 28 or 60 film-coated tablets in a container containing desiccant sachet or in blister.

Not all pack sizes may be marketed

## Marketing Authorisation Holder and Manufacturer:

### Marketing Authorisation Holder:

Pharmathen S.A.  
6 Dervenakion str.  
15351 Pallini, Attiki  
Grækenland

### Manufacturer:

Pharmathen S.A.  
6, Dervenakion str.



15351 Pallini, Attiki  
Greece

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Denmark:	Monotop
Germany:	Topiramat AURUS 25 mg Filmdabletten
	Topiramat AURUS 50 mg Filmdabletten
	Topiramat AURUS 100 mg Filmdabletten
	Topiramat AURUS 200 mg Filmdabletten
Ireland:	Topiramat Pharmathen 25 mg film-coated tablets
	Topiramat Pharmathen 50 mg film-coated tablets
	Topiramat Pharmathen 100 mg film-coated tablets
	Topiramat Pharmathen 200 mg film-coated tablets

**This leaflet was last approved in 05/2013**