

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Topit 25 mg film-coated tablets  
Topit 50 mg film-coated tablets  
Topit 100 mg film-coated tablets  
Topit 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.
- 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

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

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

#### **1. What Topit is and what it is used for**

Topit 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 aged 2 years and above
- to prevent migraine headaches in adults

#### **2. What you need to know before you take Topit**

##### **Do not take Topit**

- if you are allergic (hypersensitive) 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 effective contraception (see section ‘pregnancy and breastfeeding’ for further information).

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

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Topit 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)
- are pregnant or could become pregnant (see section “pregnancy and breast-feeding” for further information)

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

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 Topit.

You may lose weight if you use Topit 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-epileptic medicines such as Topit have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

### **Other medicines and Topit**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Topit and certain other medicines can affect each other. Sometimes the dose of some of your other medicines or Topit 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. Topit may make your birth control pills less effective.

Tell your doctor if your menstrual bleeding changes while you are taking birth control pills and Topit.

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, St. John’s Wort (*Hypericum perforatum*) (a herbal preparation used to treat depression).

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

### **Topit with food and drink**

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

### **Pregnancy, 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 for advice before taking this medicine.

Your doctor will decide if you can take Topit. As with other antiepilepsy medicines, there is a risk of harm to the unborn child if Topit is used during pregnancy. Make sure you are very clear about the risks and the benefits of using Topit for epilepsy during pregnancy.

You should not take Topit 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 Topit must tell the doctor as soon as possible if the baby experiences anything unusual.

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

### **Driving and using machines**

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

**Topit 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 Topit**

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

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

### **If you take more Topit than you should**

- See a doctor right away. Take the medicine pack with you.
- You may feel sleepy, tired or less alert; lack coordination; have difficulty speaking or concentrating; have double or blurred vision; feel dizzy due to low blood pressure; feel depressed or agitated; or have abdominal pain, or seizures (fits).

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

### **If you forget to take Topit**

- 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 Topit**

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 medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

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

**Tell your doctor, or seek medical attention immediately if you have the following side effects:**

### **Very common (may affect more than 1 in 10 people)**

- Depression (new or worse)

### **Common (may affect up to 1 in 10 people)**

- Seizures (fits)
- Anxiety, irritability, changes in mood, confusion, disorientation
- Problems with concentration, slowness of thinking, loss of memory, problems with memory (new onset, sudden change or increased severity)
- Kidney stone, frequent or painful urination

### **Uncommon (may affect up to 1 in 100 people)**

- Increased acid level in the blood (may cause troubled breathing including shortness of breath, loss of appetite, nausea, vomiting, excessive tiredness, and fast or uneven heart beats)
- Decreased or loss of sweating
- Having thoughts of serious self-harm, trying to cause serious self-harm

### **Rare (may affect up to 1 in 1,000 people)**

- Glaucoma – blockage of fluid in eye causing increased pressure in the eye, pain, or decreased vision

**Other side effects include the following, if they get serious, please tell your doctor or pharmacist**

### **Very common (may affect more than 1 in 10 people)**

- Stuffy, runny nose or sore throat
- Tingling, pain and/or numbness of various body parts
- Sleepiness, tiredness
- Dizziness
- Nausea, diarrhoea
- Weight loss

### **Common (may affect up to 1 in 10 people)**

- Anaemia (low blood count)
- Allergic reaction (such as skin rash, redness, itching, facial swelling, hives)

- Loss of appetite, decreased appetite
- Aggression, agitation, anger
- Difficulty falling or staying asleep
- Problems with speech or speech disorder, slurred speech
- Clumsiness or lack of coordination, feeling of unsteadiness when walking
- Decreased ability to complete routine tasks
- Decreased, loss of, or no sense of taste
- Involuntary trembling or shaking; rapid, uncontrollable movement of the eyes
- Visual disturbance, such as double vision, blurred vision, decreased vision, difficulty focusing
- Sensation of spinning (vertigo), ringing in the ears, ear pain
- Shortness of breath
- Cough
- Nose bleeds
- Fever, not feeling well, weakness
- Vomiting, constipation, abdominal pain or discomfort, indigestion, stomach or intestinal infection
- Dry mouth
- Hair loss
- Itching
- Joint pain or swelling, muscle spasms or twitching, muscle aches or weakness, chest pain
- Weight gain

**Uncommon (may affect up to 1 in 100 people):**

- Decrease in platelets (blood cells that help stop bleeding), decrease in white blood cells that help to protect you against infection, decrease in potassium level in the blood
- Increase in liver enzymes, increase in eosinophils (a type of white blood cell) in the blood
- Swollen glands in the neck, armpit, or groin
- Increased appetite
- Elevated mood
- Hearing, seeing, or feeling things that are not there, severe mental disorder (psychosis)
- Showing and/or feeling no emotion, unusual suspiciousness, panic attack
- Problems with reading, speech disorder, problems with handwriting
- Restlessness, hyperactivity
- Slowed thinking, decreased wakefulness or alertness
- Reduced or slow body movements, involuntary abnormal or repetitive muscle movements
- Fainting
- Abnormal sense of touch; impaired sense of touch
- Impaired, distorted, or no sense of smell
- Unusual feeling or sensation that may precede a migraine or a certain type of seizure
- Dry eye, sensitivity of the eyes to light, eyelid twitching, watery eyes
- Decreased or loss of hearing, loss of hearing in one ear
- Slow or irregular heartbeat, feeling your heart beating in your chest
- Low blood pressure, low blood pressure upon standing (consequently, some people taking Topit may feel faint, dizzy, or may pass out when they stand up or sit up suddenly)
- Flushing, feeling warm
- Pancreatitis (inflammation of the pancreas)
- Excessive passing of gas or wind, heartburn, abdominal fullness or bloating

- Bleeding gums, increased saliva, drooling, breath odour
- Excessive intake of fluids, thirst
- Skin discolouration
- Muscle stiffness, pain in side
- Blood in urine, incontinence (lack of control) of urine, urgent desire to urinate, flank or kidney pain
- Difficulty getting or keeping an erection, sexual dysfunction
- Flu-like symptoms
- Cold fingers and toes
- Feeling drunk
- Learning disability

**Rare (may affect up to 1 in 1,000 people)**

- Abnormally elevated mood
- Loss of consciousness
- Blindness in one eye, temporary blindness, night blindness
- Lazy eye
- Swelling in and around the eyes
- Numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to the cold
- Inflammation of the liver, liver failure
- Stevens Johnson syndrome, a potentially life-threatening condition that may present with sores in multiple mucosal sites (such as the mouth, nose, and eyes), a skin rash, and blistering
- Abnormal skin odour
- Discomfort in your arms or legs
- Kidney disorder

**Not known (frequency cannot be estimated from the available data)**

- 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.
- Toxic epidermal necrosis, a life-threatening condition related to, yet more severe than, Stevens-Johnson syndrome, characterized by widespread blistering and sloughing of the outer layers of the skin (see rare side effects)

**Children and adolescents**

The side effects in children are generally similar to those seen in adults. However, some side effects are either seen more frequently in children and/or can be more severe in children than in adults. Side effects which may be more severe include decreased or loss of sweating and increase of the acid level in the blood. Side effects which may occur more frequently in children include upper respiratory tract illnesses.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.imb.ie](http://www.imb.ie); e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Topit**

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

Do not use Topit after the expiry date which is stated on the label and the outer carton after EXP. The expiry date refers to the last day of the month.

HDPE containers: 1 month after first opening.

Do not store above 25 °C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

### **What Topit contains**

The active substance is topiramate.

Topit 25 mg film-coated tablets

Each film-coated tablet contains 25 mg of topiramate.

Topit 50 mg film-coated tablets

Each film-coated tablet contains 50 mg of topiramate.

Topit 100 mg film-coated tablets

Each film-coated tablet contains 100 mg of topiramate.

Topit 200 mg film-coated tablets

Each film-coated tablet contains 200 mg of topiramate.

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose, starch, sodium starch glycolate, magnesium stearate, hypromellose, titanium dioxide (E 171), macrogol, polysorbate 80. Topit 50/200 mg film-coated tablets: yellow iron oxide (E 172)

### **What Topit looks like and contents of the pack**

Film-coated tablets

Topit 25 mg film-coated tablet:

White, round shaped, film-coated tablet, plain on both sides.

Topit 50 mg film-coated tablet:

Yellow, round shaped, film-coated tablet, plain on both sides.

Topit 100 mg film-coated tablet:

White, round shaped, film-coated tablet, plain on both sides.

Topit 200 mg film-coated tablet:

Yellow, round shaped, film-coated tablet, plain on both sides.

Blisters: 5, 6, 10, 20, 60 and 100 film-coated tablets.

HDPE container with PP cap with desiccant: 20, 28, 50, 60, 100 and 200 film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturers**

*Marketing Authorisation Holder:*

Rowex Ltd., Bantry, Co. Cork, Ireland

*Manufacturers:*

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

Lek S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

Salutas Pharma GmbH, Dieselstrasse 5, 70839 Gerlingen, Germany.

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.

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

Austria:	Topiramat Sandoz 25 mg - Filmtabletten Topiramat Sandoz 50 mg - Filmtabletten Topiramat Sandoz 100 mg - Filmtabletten Topiramat Sandoz 200 mg - Filmtabletten
Belgium:	Topiramate Sandoz 25 mg filmomhulde tabletten Topiramate Sandoz 50 mg filmomhulde tabletten Topiramate Sandoz 100 mg filmomhulde tabletten Topiramate Sandoz 200 mg filmomhulde tabletten
Czech Republic:	Topiramat Sandoz 25 mg, tbl. Topiramat Sandoz 50 mg, tbl. Topiramat Sandoz 100 mg, tbl. Topiramat Sandoz 200 mg, tbl.
Estonia:	Topiramate Sandoz 25mg Topiramate Sandoz 50mg Topiramate Sandoz 100mg
Finland:	Topiramat Sandoz 25 mg tabletti, kalvopäällysteinen Topiramat Sandoz 50 mg tabletti, kalvopäällysteinen Topiramat Sandoz 100 mg tabletti, kalvopäällysteinen Topiramat Sandoz 200 mg tabletti, kalvopäällysteinen
Germany:	Topiramat Sandoz 25 mg Filmtabletten Topiramat Sandoz 50 mg Filmtabletten Topiramat Sandoz 100 mg Filmtabletten Topiramat Sandoz 200 mg Filmtabletten
Greece:	LETOP
Hungary:	Topiramat Sandoz 25 mg filmdobéta Topiramat Sandoz 50 mg filmdobéta Topiramat Sandoz 100 mg filmdobéta Topiramat Sandoz 200 mg filmdobéta
Ireland:	Topit 25 mg Film-Coated Tablets Topit 50 mg Film-Coated Tablets Topit 100 mg Film-Coated Tablets Topit 200 mg Film-Coated Tablets

Italy:	TOPIRAMATO SANDOZ 25 mg compresse rivestite con film TOPIRAMATO SANDOZ 50 mg compresse rivestite con film TOPIRAMATO SANDOZ 100 mg compresse rivestite con film TOPIRAMATO SANDOZ 200 mg compresse rivestite con film
Latvia:	Topiramate Sandoz 25 mg apvalkotās tabletes Topiramate Sandoz 50 mg apvalkotās tabletes Topiramate Sandoz 100 mg apvalkotās tabletes
Lithuania:	Topiramate Sandoz 25 mg plėvele dengtos tabletės Topiramate Sandoz 50 mg plėvele dengtos tabletės Topiramate Sandoz 100 mg plėvele dengtos tabletės Topiramate Sandoz 200 mg plėvele dengtos tabletės
The Netherlands:	Topiramaat Sandoz 25 mg tabletten Topiramaat Sandoz 100 mg tabletten Topiramaat Sandoz 200 mg tabletten
Norway:	Topiramat Sandoz 25 mg filmdrasjerte tabletter Topiramat Sandoz 50 mg filmdrasjerte tabletter Topiramat Sandoz 100 mg filmdrasjerte tabletter Topiramat Sandoz 200 mg filmdrasjerte tabletter
Poland:	TopiLek 25 TopiLek 50 TopiLek 100 TopiLek 200
Portugal:	Topiramato SANDOZ 25 mg Comprimidos Topiramato SANDOZ 50 mg Comprimidos Topiramato SANDOZ 100 mg Comprimidos Topiramato SANDOZ 200 mg Comprimidos
Slovak Republic:	Topiramát Sandoz 25 mg filmom obalené tablety Topiramát Sandoz 50 mg filmom obalené tablety Topiramát Sandoz 100 mg filmom obalené tablety
Slovenia:	LETOP 25 mg tablete LETOP 50 mg tablete LETOP 100 mg tablete LETOP 200 mg tablete
Sweden:	Topiramat Sandoz
United Kingdom:	Topiramate 25mg tablets Topiramate 50mg tablets Topiramate 100mg tablets Topiramate 200mg tablets

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