





ANNEXURE - I  
ART WORK APPROVAL FORM

(Ref. SOP. No.: DFD080)

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**Driving and using machines**

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

**Topiramate Tablets 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 TOPIRAMATE TABLETS**

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

**If you take more Topiramate Tablets 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 Topiramate Tablets.

**If you forget to take Topiramate Tablets**

- 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 Tablets**

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.

**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 (particularly in young children who are exposed to high temperatures)
- Having thoughts of serious self-harm, trying to cause serious self-harm
- Loss of part of the field of vision

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

- 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.
- Glaucoma – blockage of fluid in eye causing increased pressure in the eye, pain, or decreased vision
- Difficulty thinking, remembering information, or solving problems, being less alert or aware, feeling very sleepy with low energy – these symptoms may be a sign of a high level of ammonia in the blood (hyperammonemia), which can lead to a change in brain function (hyperammonemic encephalopathy).

**Not known: frequency cannot be estimated from the available data:**

- 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).
- Inflammation of the eye (uveitis) with symptoms such as eye redness, pain, sensitivity to light, runny eyes, seeing small dots or getting blurred 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, abnormal behaviour
- 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 movements 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 Topiramate Tablets 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
- 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.

**Children**

The side effects in children are generally similar to those seen in adults, but the following side effects may be more common in children than adults:

- Problems with concentration
- Increased acid level in the blood
- Having thoughts of serious self-harm
- Tiredness
- Decreased or increased appetite
- Aggression, abnormal behaviour
- Difficulty falling or staying asleep
- Feeling of unsteadiness when walking
- Not feeling well
- Decrease in potassium level in the blood
- Showing and/or feeling no emotion
- Watery eyes
- Slow or irregular heartbeat

Other side effects that may occur in children are:

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

- Sensation of spinning (vertigo)
- Vomiting
- Fever

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

- Increase in eosinophils (a type of white blood cell) in the blood
- Hyperactivity
- Feeling warm
- Learning disability

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE TOPIRAMATE TABLETS**

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

Do not use this medicine after the expiry date which is stated on the carton after (Exp.). The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions. Store in the original package.

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 Topiramate Tablets contain:**

The active substance is topiramate.  
Each film-coated tablet contains 25 mg, 50 mg, 100 mg or 200 mg of topiramate.

**Tablet core:**

The ingredients are lactose monohydrate, pregelatinized starch, microcrystalline cellulose, sodium starch glycolate and magnesium stearate.

**Film-coating:**

Topiramate 25 mg Tablets are coated with the ingredients of titanium dioxide, hypromellose, polysorbate 80 and indigo carmine aluminium lake (E132).  
Topiramate 50 & 100 mg Tablets are coated with the ingredients of titanium dioxide, hypromellose, polysorbate 80, iron oxide yellow (E172) and iron oxide red (E172).  
Topiramate 200 mg Tablets are coated with the ingredients of titanium dioxide, hypromellose, polysorbate 80 and iron oxide red (E172).

**What Topiramate Tablets look like and the contents of the pack:**

Topiramate 25 mg: white coloured, circular, biconvex film-coated tablets.  
Topiramate 50 mg: light-orange coloured, circular, biconvex film-coated tablets.  
Topiramate 100 mg: orange coloured, circular, biconvex film-coated tablets.  
Topiramate 200 mg: pink coloured, biconvex, caplet-shaped film-coated tablets.  
Topiramate Tablets are available in containers of 60, 100 & 200 film-coated tablets and blister packs of 28, 56, 60 & 84 film-coated tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

Cadila Pharmaceuticals (UK) Limited  
Amba House 4th Floor,  
Kings Suite 15 College Road,  
Harrow, Middlesex,  
HA1 1BA, United Kingdom

**Manufacturer:**

Ennogen Healthcare Limited  
Unit G2-G4, Riverside Industrial Estate  
Riverside Way, Dartford DA1 5BS, UK

**This leaflet was last revised in January 2025.**



Open Size : 240 x 485 mm | Folded Size : 40 x 70 mm  
Color : Black

BS-10/02/25-V07  
BS-27/01/25-V06  
BS-23/01/25-V05  
BS-10/03/23-V04  
BS-21/12/22-V03  
BS-20/12/22-V02  
BS-14/12/22-V01

CADILA PHARMACEUTICALS LTD.

Product TOPIRAMATE Market Export (Cadila Pharma - UK) Dimension 240 x 485 mm  
Item code OETD0560 Mfg. Location Dholka Component leaflet - Back Side Change part Layout: NA  
Substrate: 28 gsm Bible paper printed pack insert (Folding size: 40 x 70 mm) with patient card pasted through perforated Tape  
Superseded item code No. : NA Color : Black No. of. Colors : 01 Pharma Code : 4457  
Version : 00 Reason for issue : New Artwork







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ART WORK APPROVAL FORM

(Ref. SOP. No.: DFD080)

<p>▼ This medicinal product is subject to additional monitoring. Report any side effects to <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Important information for all patients who could become pregnant</p> <p>Contraception and Pregnancy Prevention – Important information to know</p>	<ul style="list-style-type: none"><li>•Topiramate is an effective medicine for epilepsy and prevention of migraine.</li><li>•Topiramate can seriously harm a baby when taken during pregnancy.</li><li>•Use effective birth control (contraception) at all times during your treatment with topiramate and for at least 4 weeks after the last dose.</li><li>•Discuss with your doctor about which method of birth control is most suitable for you.</li><li>•It is important to visit your doctor to review your treatment at least once each year.</li></ul>	<p><b>What you must do</b></p> <ul style="list-style-type: none"><li>•Read the package leaflet carefully before use.</li><li>•Read the <b>Patient Guide</b> for the topiramate pregnancy prevention programme. You should have received a copy from your doctor or it can be found online at <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> by entering “topiramate” in the search box and then clicking on “Risk Materials”.</li><li>•If you are <b>thinking about having a baby</b>, make an appointment with your GP. Do not stop using topiramate and contraception before you have talked to your doctor.</li></ul> <p>OETD0560</p>	<ul style="list-style-type: none"><li>• If you <b>think you are pregnant and are taking topiramate for epilepsy</b>, do not stop using topiramate. This may cause your seizures to start again or happen more often and last longer. Make an urgent appointment with your GP or epilepsy team (within a few days).</li><li>• If you <b>think you are pregnant and are taking topiramate for migraine prevention</b>, stop taking topiramate straight away and contact your GP.</li></ul>
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Color : Black

Back

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BS-27/01/25-V06  
BS-23/01/25-V05  
BS-10/03/23-V04  
BS-21/12/22-V03  
BS-20/12/22-V02  
BS-14/12/22-V01

CADILA PHARMACEUTICALS LTD.

Product	TOPIRAMATE	Market	Export (Cadila Pharma - UK)	Dimension	240 x 485 mm
Item code	OETD0560	Mfg. Location	Dholka	Component	leaflet - Back Side
Change part Layout:		NA			
Substrate: 28 gsm Bible paper printed pack insert (Folding size: 40 x 70 mm) with patient card pasted through perforated Tape					
Superseded item code No. :		NA		Color :	Black
No. of. Colors :		01		Pharma Code : 4457	
Version :		00		Reason for issue : New Artwork	