Package leaflet: Information for the patient

Topiramate Mylan 25 mg film-coated tablets
Topiramate Mylan 50 mg film-coated tablets
Topiramate Mylan 100 mg film-coated tablets
Topiramate Mylan 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 side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Topiramate is and what it is used for

Topiramate 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 Topiramate

Do not take Topiramate:
- 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 if you are a woman of childbearing potential unless you are using effective contraception (see section 'pregnancy and breast-feeding' for further information). You should talk to your doctor about the best kind of contraception to use while you are taking this medicine.

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Topiramate if you:
- have kidney problems, especially:
  - kidney stones
  - high levels of calcium in your urine
  - if a member of your family has or ever had kidney stones
  - or you are getting kidney dialysis

- have a history of blood and body fluid abnormality (metabolic acidosis) which may be associated with:
  - severe breathing problems
  - severe or prolonged diarrhoea
  - surgery
  - or a high fat, low carbohydrate (ketogenic) diet
- have liver problems
- have eye problems, especially glaucoma
- have a growth problem
- are taking Topiramate to treat epilepsy and you are pregnant or a woman of childbearing potential (see section 'pregnancy and breast-feeding' for further information)

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

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.

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

Topiramate can cause serious skin reactions, tell your doctor immediately if you develop a skin rash and/or blisters (see also section 4 'Possible side effects').

Topiramate may in rare cases cause high levels of ammonia in the blood (seen in blood tests) which can lead to a change in brain function, especially if you are also taking a medicine called valproic acid or sodium valproate. Since this may be a severe condition, tell your doctor immediately if the following symptoms occur (see also section 4 'Possible side effects'):
- difficulty thinking, remembering information, or solving problems
- being less alert or aware
- feeling very sleepy with low energy

At higher doses of Topiramate, the risk of developing these symptoms may increase.

You may experience an increase in fits (seizures) or have a different type of seizure; if this happens, talk to your doctor.

If you develop any problems with your vision and/or your eyes, you should contact your doctor immediately.

Other medicines and Topiramate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Topiramate and certain other medicines can affect each other. Sometimes the dose of some of your other medicines or Topiramate 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 e.g. diazepam).

- birth control pills. Topiramate may make your birth control pills less effective. You should talk to your doctor about the best kind of contraception to use while you are taking Topiramate.

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

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, haloperidol (used to treat mental health problems), metformin, pioglitazone, glibenclamide, (used to treat diabetes), amitriptyline, moclobemide, imipramine (used to treat depression), propranolol, diltiazem, digoxin, (used to treat heart conditions), flunarizine, (used to treat migraine), proguanil (used to prevent malaria), omeprazole (used to treat indigestion), venlafaxine (a medicine used to treat depression) and St. John's wort (*Hypericum perforatum*) (a herbal preparation used to treat depression), warfarin (used to thin the blood).

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

Topiramate with alcohol
You can take Topiramate with or without food. You should avoid drinking alcohol when taking Topiramate.

Pregnancy, breast-feeding and fertility
Migraine prevention:

Topiramate can harm an unborn baby. You must not use this medicine if you are pregnant. You must not use Topiramate for migraine prevention if you are a woman of childbearing potential unless you are using effective contraception. Talk to your doctor about the best kind of contraception and whether this medicine is suitable for you. Before the start of treatment with Topiramate a pregnancy test should be performed.

Treatment of epilepsy:

If you are a woman of childbearing potential you should talk to your doctor about other possible treatments instead of Topiramate. If the decision is made to use this medicine, you should use effective contraception. Talk to your doctor about the best kind of contraception to use while you are taking Topiramate. Before the start of treatment with Topiramate a pregnancy test should be performed. Talk to your doctor if you wish to become pregnant.

As with other anti-epilepsy medicines, there is a risk of harm to the unborn child if topiramate is used during pregnancy. Make sure you are very clear about the risks and the benefits of using Topiramate for epilepsy during pregnancy.

- If you take Topiramate during pregnancy, your baby has a higher risk for birth defects, particularly, cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth). Newborn boys may also have a malformation of the penis (hypospadia). These defects can develop early in pregnancy, even before you know you are pregnant.
- If you take Topiramate during pregnancy, your baby may be smaller than expected at birth. Talk to your doctor if you have questions about this risk during pregnancy.
- There may be other medicines to treat your condition that have a lower risk of birth defects.
- Tell your doctor straight away if you become pregnant while taking this medicine. You and your doctor should decide if you will continue to take Topiramate while you are pregnant.

Breast-feeding

The active substance in this medicine (topiramate) passes into breast milk. Effects have been seen in breastfed babies of treated mothers, including diarrhoea, feeling sleepy, feeling irritable, and poor weight gain. Therefore, your doctor will discuss with you whether you abstain from breast-feeding or whether to abstain from treatment with Topiramate. Your doctor will take into account the importance of the medicine to the mother and the risk for the baby.. Mothers who breast-feed while taking topiramate must tell the doctor as soon as possible if the baby experiences anything unusual.

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

Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

[For 200 mg tablets only]
Sunset yellow aluminum lake (E110) and allura red aluminium lake (E129) content
This medicinal product contains sunset yellow aluminium lake (E110) and allura red aluminium lake (E129), which may cause allergic reactions.

3. How to take Topiramate

Always take this medicine exactly as your doctor or pharmacist 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 can be taken before, during, or after a meal. Drink plenty of fluids during the day to especially if exercising or during warm weather or activities where you will become hot prevent kidney stones while taking topiramate. Other forms of this medicine may be available which may be more suitable for patients who cannot swallow tablets, ask your doctor or pharmacist.

If you take more Topiramate 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.

If you forget to take Topiramate
- 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
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, confusion, disorientation, changes in mood or behaviour, including anger, nervousness, sadness
- 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, calcium deposits in the kidneys
- Allergic reaction (such as skin rash, redness, itching and facial swelling, including swelling of the nose, lips, eyelids and tongue, hives)
- Decreased vision

Uncommon (may affect up to1 in 100 people):
- Increased number of infections, with sore throat, fever, chills or mouth ulcers, which may be due to a decrease in white blood cells which may be seen in blood tests
- 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, which can cause a serious rise in temperature with hot dry skin, feeling and being sick, headache, dizziness and fainting
- Having thoughts of serious self-harm, trying to cause serious self-harm
- Hearing, seeing or feeling things that are not there, severe mental disorder (psychosis)
- Loss of control of muscle movements which affect walking in a straight line, which will show up in medical tests
- Decreased or loss of hearing
- Severe pain in the centre of the abdomen (tummy) which may be swollen, with fever, feeling or being sick (pancreatitis, inflammation of the pancreas)
- Pain in the kidney area and/or bladder caused by a ‘kidney’ stone or crystals which can move into the bladder or other parts of the urinary system. You may experience severe pain in the back and lower stomach and pass little or no urine.

Rare (may affect up to 1 in 1000 people):
- Decrease in the amount of water that you pass, confusion, muscle cramps, uneven heartbeat (renal tubular acidosis)
- Feeling irritable and excitable with mood changes and behaving out of character
- Glaucoma which is a blockage of fluid in the eye causing increased pressure in the eye, pain and decreased vision, blindness in one eye, temporary blindness
- Yellowing of the skin and eyes (Inflammation of the liver, liver failure)
- Severe skin reaction, including Stevens-Johnson syndrome, a life threatening skin condition in which the upper layer of the skin separates from the lower, that may present with sores in multiple mucosal sites (such as the mouth, nose, and eyes) and erythema multiforme, a condition of raised red spots that can blister
- 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).
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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 may notice a change or decrease in your vision.
- Toxic epidermal necrolysis, a life-threatening condition related to, yet more severe than Stevens-Johnson syndrome, characterised by widespread blistering and sloughing of the outer layers of the skin (see rare side effects)

Other possible side effects

Very common (may affect more than 1 in 10 people):
- Weight loss
- Tingling, pain and/or numbness of various body parts
- Drowsiness, sleepiness or tiredness
- Dizziness
- Diarrhoea
- Feeling sick (nausea)
- Stuffy, runny nose and sore throat

Common (may affect up to 1 in 10 people):
- Weight gain
- Decrease or loss of appetite
- Feeling tired, breathless with pale skin- this may be caused by reduced number of red blood cells
- 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
- Uncontrolled trembling or shaking in the arms, hands or legs
- Reduced sense of touch or sensation
- Uncontrollable movement of the eyes
- Distorted sense of taste
- Visual disturbance, such as blurred vision, double vision, difficulty focussing
- Sensation of spinning, ringing sound in the ears, ear pain
- Shortness of breath
- Nose bleeds
- Being sick (vomiting)
- Constipation
- Gastritis, stomach pain or discomfort
- Indigestion
- Dry mouth
- Tingling or numbness of the mouth
- Hair loss
- Joint pain or swelling
- Muscle spasms, muscle twitching, muscle weakness or muscle pain
- Chest pain (which is caused by the muscles and bones in the chest)
- Fever
- Loss of strength
- General feeling of feeling unwell
- Cough

Uncommon (may affect up to 1 in 100 people):
- Abnormal blood counts, including reduced platelet count (you may bruise or bleed more easily), or increased eosinophils
- Increase in liver enzymes
- Elevated mood
- Showing and feeling no emotion, unusual suspiciousness, panic attack
- Irregular heartbeat or slowness of the heart beat
- Swollen glands in the neck, armpit or groin
- Problems with verbal communication

- Drooling
- Restlessness or increased mental and physical activity
- • Decreased wakefulness or alertness
- Unusual feeling or sensation that may precede a migraine or a certain type of seizure
- Loss of consciousness
- Fainting and feeling faint
- Excessive sleepiness
- Slow or diminished movements, uncontrolled repetitive twitching of muscles
- Disturbed or poor quality sleep (e.g. waking early in the morning)
- Impaired or distorted sense of smell
- Problems with handwriting or speech, such as stuttering or constantly repeating words
- Feeling of movement under the skin
- Eye problems including dry eyes, light sensitivity, involuntary twitching, tearing, enlarged pupil, seeing flashes of light, abnormal sensations in the eye
- Hoarseness of the voice
- Gas or wind
- Heartburn
- Loss of sensitivity to touch or altered sense of touch that may feel unpleasant, which can affect the mouth of face
- Bleeding gums
- Fullness or bloating
- Painful or burning sensations in the mouth
- Breath odour
- Loss of taste
- Leakage of urine and/or stools, blood in urine
- Urgent desire to urinate
- Skin discolouration
- Localised swelling in the skin
- Swelling of the face
- Swelling of the joints
- Musculoskeletal stiffness or muscle fatigue
- 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, which may make you feel dizzy or faint
- Breathlessness, especially after exercise
- Hot flushing, feeling warm
- Flu like illness
- Cold extremities (e.g. hands and face)
- Feeling drunk
- Problems with learning
- Disturbances in sexual function (erectile dysfunction, loss of libido)
- Hallucinations
- Decreased verbal communication
- Feeling tearful or crying

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

- Feeling hopeless
- Uncontrolled shaking which may affect the tongue, hands or head when performing tasks
- Decreased bodily movement, being unreactive
- Excessive skin sensitivity
- Impaired sense of smell
- Odour
- Swelling in the tissues around the eye, problems with vision in dim light, lazy eye
- Raynaud's syndrome. A disorder affecting the blood vessels, in the fingers, toes, ears and causing pain and cold sensitivity

- Blood bicarbonate decreased which will show up in blood tests

Not Known (frequency cannot be estimated from the available data):
- Swelling of the clear covering of the eye surface (conjunctiva)
- Inflammation of the eye (uveitis) with symptoms such as eye redness, pain, sensitivity to light, runny eyes, seeing small dots or getting blurred vision.

Additional side effects in 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 or pharmacist. This includes any 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Topiramate

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 blister and the carton after EXP. The expiry date refers to the last day of that month.

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

Do not use this medicine if you notice discolouration of the tablets.

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

The other ingredients are:
- Tablet core: microcrystalline cellulose, povidone K29-32, silica colloidal anhydrous, sodium starch glycolate (type A), magnesium stearate.
- Film-coat: titanium dioxide (E171), hypromellose (E464), macrogol 400, polysorbate 80 (E433) (25 mg only), iron oxide yellow (E172) (50 mg, 100 mg only), allura red (E129), sunset yellow (E110) and indigo carmine (E132) (200 mg only) (see section 2 “Topiramate 200 mg contains sunset yellow aluminium lake (E110) and allura red aluminium lake (E129)”).

What Topiramate looks like and contents of the pack
Your medicine comes in the form of a film-coated tablet that should look like the following:

25 mg: White, round, film-coated tablet with sides that curve outwards, marked with “G” on one side and “TO” over “25” on the other.

50 mg: Yellow, round, film-coated tablet with sides that curve outwards, marked with “G” on one side and “TO” over “50” on the other.

100 mg: Yellow, round, film-coated tablet with sides that curve outwards, marked with “G” on one side and “TO” over “100” on the other.

200 mg: Red, round, film-coated tablet with sides that curve outwards, marked with “G” on one side and “TO” over “200” on the other.

The medicinal product is available in aluminium foil blisters in pack sizes of 10, 15, 20, 28, 30, 50, 60, 90, 100, 200 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder
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