Package leaflet: Information for the patient
Topiramate Accord 25 mg film-coated tablets
Topiramate Accord 50 mg film-coated tablets
Topiramate Accord 100 mg film-coated tablets
Topiramate Accord 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 topiramate tablets are and what they are used for
2. What you need to know before you take topiramate tablets
3. How to take topiramate tablets
4. Possible side effects
5. How to store topiramate tablets
6. Contents of the pack and other information

1. What topiramate tablets are and what they are 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 over age 2
- to prevent migraine headaches in adults

2. What you need to know before you take topiramate tablets

Do not take topiramate tablets:
- 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 “Pregnancy, breastfeeding and fertility” section for further information).

If you are not sure if the above applies to you, talk to your doctor or pharmacist before taking topiramate tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking topiramate tablets 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 “pregnancy, breastfeeding and fertility” - section for further information)
If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking topiramate tablets.

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 this medicine.

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 anti-epileptic medicines such as topiramate have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

**Other medicines and topiramate tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, Topiramate tablets and certain other medicines can affect each other. Sometimes the dose of some of your other medicines or this medicine 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. This medicine 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.

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 and 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 topiramate.

**Topiramate tablets with food and drink**

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

**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 or pharmacist for advice before taking this medicine. Your doctor will discuss use of contraceptives with you, as well as discussing whether Topiramate is suitable for you. As with other anti-epileptic 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.
You should not take topiramate 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 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.

**Topiramate tablets contain 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.
Warning! Each bottle contains a desiccant capsule. This a small canister on which “Do not eat” is written. Do not eat this.

### 3. How to take topiramate tablets

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 exactly as prescribed. 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 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.

**If you forget to take topiramate tablets**
Take the missed dose as soon as you remember. If it is almost time for your next dose, do not take the missed dose but simply take your next dose at the normal time. If you miss two or more doses, contact your doctor.
Do not take a double dose to make up for forgotten dose.

**If you stop taking topiramate tablets**
You may have more fits or sudden worsening of the headaches. It is important that you keep taking your tablets until your doctor tells you to stop. If the doctor decides to stop your treatment they will usually do so gradually over a period of a few weeks. It is important that you follow what the doctor tells you to do.
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.

Stop taking this medicine and tell your doctor, or go to a hospital straight away if you have any of 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
- Loss of part of the field of vision

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 side effects (may affect more than 1 in 10 people):**
- weight loss
- tingling, pain and/or numbness of various body parts
- dizziness
- diarrhoea
- nausea (feeling sick)
- stuffy, runny nose and sore throat
- sleepiness, tiredness

**Common side effects (may affect up to 1 in 10 people):**
- Anaemia (low number of red blood cells)
- 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 in the arms, hands or legs; rapid, uncontrollable movements of the eyes
• Visual disturbance, such as blurred vision, double 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 side effects (may affect upto 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 Topamax 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 side effects (may affect upto 1 in 1,000 people):
• Abnormally elevated mood
• Loss of consciousness
• Blindness in one eye, temporary blindness, night blindness
• Lazy eye
• 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 month, nose, and eyes), a skin rash, and blistering
• Anbormal 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**
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. 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 sight and reach of children. Do not use this medicine after the expiry date, which is stated on the carton and bottle or blister after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C. Keep the container tightly closed 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 to 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 topiramate.
Each film-coated tablet contains 50 mg topiramate.
Each film-coated tablet contains 100 mg topiramate.
Each film-coated tablet contains 200 mg topiramate.

The other ingredients are lactose monohydrate (see section 2: topiramate tablets contain lactose), cellulose microcrystalline, starch, pregelatinised (i.e. potato starch), croscarmellose sodium and magnesium stearate.
- The 25 mg tablets are coated with hypromellose, titanium dioxide (E171) and macrogol 6000.
- The 50 mg and 100 mg tablets are coated with hypromellose, titanium dioxide (E171), macrogol 6000 and iron oxide yellow (E172)
- The 200 mg tablets are coated with hypromellose, titanium dioxide (E171), macrogol 6000 and iron oxide red (E172).

What topiramate tablets look like and contents of the pack
Film-coated tablet.
Topiramate Accord is available in four strengths containing either 25 mg, 50 mg, 100 mg and 200 mg topiramate.
The 25 mg film-coated tablets are white round and biconvex, with bevelled edges and embossed TP on one side and 25 on the other.
The 50 mg film-coated tablets are light yellow round and biconvex with bevelled edges and embossed TP on one side and 50 on the other.
The 100 mg film-coated tablets are dark yellow round and biconvex, with bevelled edges and embossed TP on one side and 100 on the other.
The 200 mg film-coated tablets are red, round and biconvex, with bevelled edges and embossed TP on one side and 200 on the other.
Topiramate film-coated tablets are available in aluminium/aluminium blisters in packs sizes of 10, 14, 20, 28, 30, 50, 56, 60, 100, 120 and 200 film-coated tablets or in high density polyethylene (HDPE) bottles fitted with a white opaque polypropylene child resistant closure with wad having induction sealing liner supplied in cardboard cartons in pack sizes of 14, 30, 60, 100 and 200 film-coated tablets.
In each container there is a desiccant canister, which should not be swallowed.
Not all pack sizes may be marketed.
Marketing authorization holder

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