

## Topiramate Accord Healthcare 25mg, 50mg, 100mg and 200mg Film-coated Tablets

**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.
- The full name of this medicine is Topiramate Accord Healthcare 25mg, 50mg, 100mg and 200mg Film-coated Tablets but within the leaflet it will be referred to as Topiramate tablets.

**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 anti-epileptic 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 tablets

**Do not take Topiramate tablets**

- if you are **allergic** to topiramate or any of the other ingredients of this medicine (listed in section 6).
- for migraine prevention: **do not take if you are pregnant** or if you are a woman of childbearing potential unless you are **using effective contraception** (see '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 Topiramate tablets.

#### Warnings and precautions

**Talk to your doctor or pharmacist before taking Topiramate tablets if you:**

- have, or have a family history of **kidney stones** or too much **calcium in the urine**
- have other **kidney problems**, or are having **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 taking Topiramate tablets 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 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 other medicine containing topiramate that is given to you as an alternative to Topiramate tablets.

You may experience **weight loss** while taking Topiramate tablets. Therefore, your weight should be checked regularly when taking this medicine. If you are losing too much weight or if a child taking this medicine is not gaining enough weight, you should consult your doctor.

You should drink plenty of fluids while taking Topiramate tablets, especially prior to and during activities such as exercise or being exposed to warm temperatures, as this may reduce the risk of heat-related side effects.

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

Topiramate tablets 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 tablets, the risk of developing these symptoms may increase.

#### Other medicines and Topiramate tablets

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 tablets 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 may make these pills less effective. You should talk to your doctor about the best kind of contraception to use while you are taking Topiramate tablets. If your menstrual bleeding changes, you have breakthrough bleeding or spotting, tell your doctor
- **other anti-epileptic** medicines (e.g. carbamazepine or phenytoin, which can reduce the effect of topiramate)
- risperidone, lithium, amitriptyline, venlafaxine, moclobamide, imipramine, St John's Wort (for **depression**)
- warfarin (used to **thin the blood**)
- hydrochlorothiazide, propranolol, diltiazem (for **angina** and **high blood pressure**)
- metformin, pioglitazone, glibenclamide (**antidiabetic medicines**)
- flunarazine (for **migraines**)
- digoxin (for **heart problems**)
- haloperidol (for **mental health problems**)
- proguanil (for **malaria**)
- omeprazole (for **stomach acid**).

#### Topiramate tablets with food, drink and alcohol

You can take Topiramate tablets with or without food. To prevent kidney stones whilst being treated with Topiramate tablets, drink plenty of fluids during the day. You should avoid drinking alcohol when taking Topiramate tablets.

#### Pregnancy and breast-feeding

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.

#### Pregnancy

Migraine prevention:

Topiramate can harm an unborn baby. You must not take topiramate if you are pregnant. You must not take 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 topiramate 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 take topiramate, 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. If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.

If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby. You and your doctor should decide if you will continue to take topiramate while you are pregnant.

You should not stop your treatment without discussing this with your doctor. Suddenly stopping may lead to breakthrough seizures which may harm you and your unborn baby. It is important that your epilepsy remains well controlled.

As with other anti-epileptic medicines, there is a risk of harm to the unborn child if topiramate is taken during pregnancy.

- If you take topiramate during pregnancy, your baby has a higher risk for birth abnormalities, 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 (hypospadias). These defects can develop early in pregnancy, even before you know you are pregnant.

- Studies with women treated with topiramate for epilepsy have shown that on average 4-5 babies in every 100 will have serious physical birth abnormalities. This compares to 2 to 3 babies in every 100 born to women who do not have epilepsy.

- The higher the dose of topiramate, the higher the risk of physical birth abnormalities but all doses carry a risk. It is important that where possible you are prescribed the lowest dose to control your epilepsy.

- Taking more than one epilepsy medicine at the same time may also increase the risk of physical birth abnormalities. This means that where possible, your doctor should consider taking one epilepsy medicine to control your epilepsy.

- 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.

#### Breast-feeding

The active substance in Topiramate tablets (topiramate) passes into human 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 tablets. 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 tablets 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 whilst taking Topiramate tablets. Do not drive or use any tools or machines without talking to your doctor first.

#### Topiramate tablets contain lecithin (soya oil)

Topiramate 50mg, 100mg and 200mg tablets contain lecithin (soya oil). If you are allergic to peanuts or soya, do not use this medicinal product.

#### Information on sodium content

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

### 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. Your doctor will usually start you on a low dose and slowly increase your dose until the best dose is found.

#### The recommended dose is:

##### If you take Topiramate tablets only for epilepsy

- Adults – starting dose of 25mg at night. The dose will be slowly increased to a maintenance dose, usually 100-200mg a day in 2 divided doses. Maximum dose of 500mg a day in 2 divided doses.
- Children over 6 years of age – starting dose of 0.5-1mg per kg of body weight at night increasing slowly to a maintenance dose, usually 100mg a day.

##### If you take Topiramate tablets with another epilepsy medicine

- Adults – starting dose of 25-50mg at night. The dose will be slowly increased to a maintenance dose, usually 200-400mg a day in 2 divided doses.
- Children over 2 years of age – starting dose of 1-3mg per kg of body weight at night increasing slowly to a maintenance dose, usually 5-9mg per kg of body weight a day in 2 divided doses.

#### Prevention of migraines

- Adults – starting dose of 25mg at night. The dose will be slowly increased to a maintenance dose of 100mg a day in 2 divided doses.
- Children – Not recommended for use in children.

Swallow whole. **Do not chew**. Take with or without food. To prevent kidney stones while taking Topiramate tablets, **drink plenty of fluids during the day**.

## If you take more Topiramate tablets than you should

See a doctor right away. Take the medicine pack with you. Signs and symptoms of overdose may include: feeling sleepy or tired, abnormal body movements, problems standing and walking, feeling dizzy due to low blood pressure, fits, double or blurred vision, changes in thinking and alertness, loss of consciousness, speech problems, changes in mood or behaviour (including anger or depression), stomach pain. 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 to make up for a forgotten dose.

## If you stop taking Topiramate tablets

**Do not stop** taking this medicine, even if you feel better, unless your doctor tells you to as 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)**

- Allergic reaction (such as skin rash, redness, itching, facial swelling, hives)
- 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 heartbeats)
- 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
- Pancreatitis (inflammation of the pancreas).

#### **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
- 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
- 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 (hyperammonaemia), which can lead to a change in brain function (hyperammonaemic encephalopathy).

### 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 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’)
- 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)**

- Nasopharyngitis (stuffy, runny nose and 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)
- Loss of appetite, decreased appetite
- Blocked or runny nose
- 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
- 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

- Excessive passing of gas or wind, heartburn, abdominal fullness or bloating
- Bleeding gums, increased saliva, drooling, breath odour, decreased, loss of, or no sense of taste
- Excessive intake of fluids, thirst
- Skin discolouration, excessive skin sensitivity
- 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.

## Children and adolescents

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, pharmacist or nurse. 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 out of the sight and reach of children.

Do not store above 25°C.

Do not use after the expiry date which is stated on the label after ‘EXP’. The expiry date refers to the last day of that month.

Topiramate tablets which are supplied in bottles must be used within 60 days of opening. There is a space provided on the bottle for you to write the date that you opened them.

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 tablet contains either 25mg, 50mg, 100mg or 200mg of topiramate. The other ingredients are mannitol, starch (pregelatinised), cellulose (microcrystalline), croscarmellose sodium, silica (colloidal anhydrous), magnesium stearate, polyvinyl alcohol, titanium dioxide, macrogols (macrogol 3350), talc. The following ingredients are also in the:

- 50mg and 100mg tablets - lecithin (Soya) (E322) and iron oxide yellow (E172).
- 200mg tablets - lecithin (Soya) (E322) and iron oxide red (E172).

### What Topiramate tablets look like and contents of the pack

25mg tablets are white, round, biconvex, tablets with 6mm diameter and engraved with the marking “V1”.

50mg tablets are light yellow, round, biconvex, tablets with 8mm diameter and engraved with the marking “V3”.

100mg tablets are yellow, round, biconvex, tablets with 10mm diameter and engraved with the marking “V4”.

200mg tablets are salmon, oval, biconvex, tablets with 9.2-18.3mm dimensions and engraved with the marking “V5”.

Pack size of 60 tablets.

### Marketing Authorisation Holder

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