

- Elevated mood
- Decreased verbal communication, disturbed or poor quality sleep
- Restlessness, hyperactivity
- Showing and/or feeling no emotion, unusual suspiciousness, panic attack
- Problems with reading or handwriting, speech disorder, problems with learning
- Slowed thinking, decreased wakefulness or alertness, feeling drunk
- Reduced or slow body movements, involuntary abnormal or repetitive muscle movements
- Abnormal sense of touch, impaired sense of touch, burning sensation, feeling of movement under the skin
- Impaired or distorted sense of smell
- Unusual feeling or sensation that may precede a migraine or a certain type of seizure (aura)
- Eye problems including dry eyes, light sensitivity, involuntary twitching, tearing and decreased vision
- Decreased hearing, loss of hearing in one ear
- Slow or irregular heartbeat, feeling your heart beating in your chest
- Low blood pressure, or decrease in blood pressure upon standing (consequently, some people taking topiramate may feel faint, dizzy, or may pass out when they stand up or sit up suddenly)
- Flushing, feeling warm
- Hoarseness of the voice
- Excessive passing of gas or wind, heartburn, abdominal fullness or bloating
- Loss of sensitivity to touch in the mouth, painful or burning sensations in the mouth, bleeding gums, increased saliva, drooling, breath odour, loss of sense of taste
- Skin discolouration, localised swelling in the skin, excessive skin sensitivity
- Swelling of the joints, muscle stiffness, muscle pain in side
- Crystals in the urine, blood in urine, leakage of urine and/or stools, urgent desire to urinate, pain in the kidney area and/or bladder caused by kidney stones
- Difficulty getting or keeping an erection, sexual dysfunction
- Increase in body temperature, flu-like symptoms
- Cold extremities (e.g. fingers and toes).

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

- Abnormally elevated mood, feeling hopeless
- Blindness in one eye, temporary blindness, night blindness, lazy eye, swelling in and around the eyes
- Decreased sense of smell, loss of smell
- Raynaud's syndrome (a disorder affecting the blood vessels, in the fingers, toes, ears and causing pain, cold sensitivity when exposed to the cold, numbness, tingling and colour change (white, blue then red) in fingers and toes)
- Abnormal skin odour
- Facial swelling
- Discomfort in your arms or legs
- Kidney stones, renal tubular acidosis (a condition when the kidneys fail to excrete acids into the urine, causing the blood to remain too acidic).

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

- Swelling due to an allergic reaction
- Swelling of the conjunctiva of the eye
- 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 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.

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
- Decreased or increased appetite, not feeling well
- Aggression, abnormal behaviour
- Difficulty falling or staying asleep, tiredness
- Feeling of unsteadiness when walking

- 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

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 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 CAPSULES

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

Store in the original container. Keep the container tightly closed in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

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 Capsules contain

The active substance is topiramate (each capsule contains 15mg or 25mg of topiramate).

The other ingredients are:

Sugar spheres (which contain sucrose, maize starch), povidone, aniseed flavour, saccharin sodium (E954), magnesium stearate, gelatin, titanium dioxide (E171) and Opadry-II-85F18378 White (which contains polyvinyl alcohol-part hydrolysed, macrogol, talc and titanium dioxide).

The black printing ink contains shellac, ethanol, isopropanol, butanol, propylene glycol, purified water, strong ammonia solution, potassium hydroxide and black iron oxide (E172).

What Topiramate Capsules look like and contents of the pack

Your medicine is in the form of hard gelatin capsules.

The 15mg hard gelatin capsules are white/white opaque with '15' printed in black on the body and '>' over 'Ti' on the cap. The capsule contains white to off-white round pellets.

The 25mg hard gelatin capsules are white/white opaque with '25' printed in black on the body and '>' over 'Ti' on the cap. The capsule contains white to off-white round pellets.

Topiramate Capsules are available in HDPE bottles containing 14, 20, 28, 56 and 60 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

This leaflet was revised in June 2024.

Other sources of information

The same information is also available on the following website: www.accord-healthcare-products.co.uk



Package leaflet: Information for the patient

Topiramate Accord 15mg and 25mg Capsules, hard

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 Capsules are and what they are used for**
- 2. What you need to know before you take Topiramate Capsules**
- 3. How to take Topiramate Capsules**
- 4. Possible side effects**
- 5. How to store Topiramate Capsules**
- 6. Contents of the pack and other information**

1. WHAT TOPIRAMATE CAPSULES ARE AND WHAT THEY ARE USED FOR

Topiramate Capsules belong to a group of medicines called "anti-epileptic medicines".

They are used:

- alone to treat seizures in adults and children over 6 years of age
- with other medicines to treat seizures in adults and children over 2 years of age
- to prevent migraine headaches in adults.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TOPIRAMATE CAPSULES

Do not take Topiramate Capsules:

- If you are allergic to topiramate or any of the other ingredients of this medicine (listed in section 6)
- Migraine prevention:
 - You must not use Topiramate Capsules if you are pregnant.
 - If you are a woman who is able to become pregnant, you must not take Topiramate Capsules, unless you use highly effective contraception (birth control) during your treatment. See below under "Pregnancy, breast-feeding and fertility – Important advice for women".
- Treatment of epilepsy:
 - You must not use Topiramate Capsules if you are pregnant, unless no other treatment gives sufficient seizure control for you.
 - If you are a woman who is able to become pregnant, you must not take Topiramate Capsules unless you use highly effective contraception (birth control) during your treatment. Do not stop taking Topiramate Capsules or your contraception until you have discussed this with your doctor. Your doctor will advise you further and make sure you are aware of and understand all of the risks of taking Topiramate Capsules during pregnancy and the risks of seizures during pregnancy. See below under "Pregnancy, breast-feeding and fertility – Important advice for women".

Make sure you read the patient guide that you will receive from your doctor.

A patient card is provided with the Topiramate Capsules package to remind you of the risks in pregnancy.

Warnings and precautions

Talk to your doctor before taking Topiramate Capsules 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 a woman who is able to become pregnant. Topiramate Capsules can harm an unborn child when taken during pregnancy. Highly effective contraception (birth control) must be used during your treatment and for at least 4 weeks after the last Topiramate Capsules dose. See section 'pregnancy and breastfeeding' for further information
- are pregnant. Topiramate Capsules can harm an unborn child when taken during pregnancy.

If you are not sure if any of the above apply to you, talk to your doctor before taking Topiramate Capsules.

If you have epilepsy, 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 Capsules.

You may lose weight if you take Topiramate Capsules so your weight should be checked regularly when taking Topiramate Capsules. If you are losing too much weight or a child taking Topiramate Capsules is not gaining enough weight, you should consult your doctor.

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

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

Topiramate Capsules 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, contact your doctor immediately if the following symptoms occur (see 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 Capsules, the risk of developing these symptoms may increase.

Other medicines and Topiramate Capsules

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 any of the following:

- medicines that impair or decrease your thinking, concentration, or muscle coordination (e.g. central nervous system depressant medicines such as muscle relaxants or sedatives)
- hormonal contraceptives. Topiramate Capsules can affect how well some hormonal contraceptives (birth control) methods work. An additional barrier method of contraception such as a condom or pessary/diaphragm should be used. You should talk to your doctor about the best kind of contraception to use while you are taking Topiramate Capsules.

Tell your doctor if your menstrual bleeding changes while you are taking hormonal contraceptives and Topiramate Capsules. Irregular bleeding may occur. In this case, continue taking the hormonal contraceptives and inform your doctor.

Keep a list of all the medicines you take. Show this list to your doctor or pharmacist before you start a new medicine.

Other medicines you should discuss with your doctor or pharmacist include: other anti-epileptic medicines, risperidone, lithium, hydrochlorothiazide, metformin, pioglitazone, glibenclamide, amitriptyline, propranolol, diltiazem, venlafaxine, flunarizine, St. John's wort (*Hypericum perforatum*) (a herbal preparation taken to treat depression) or warfarin (taken to thin the blood).

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

Topiramate Capsules with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

Important advice for women who are able to become pregnant

Topiramate Capsules can harm an unborn child. If you are a woman who is able to become pregnant, talk to your doctor about other possible treatments. Visit your doctor to review your treatment and discuss the risks at least once a year.

Migraine prevention

- For migraine, you must not use Topiramate Capsules if you are pregnant.
- For migraine, you must not use Topiramate Capsules if you are a woman who is able to become pregnant unless you are using highly effective contraception (birth control).
- Before the start of treatment with Topiramate Capsules a pregnancy test should be performed in a woman who is able to become pregnant.

Treatment of epilepsy

- For epilepsy, you must not use Topiramate Capsules if you are pregnant, unless you and your doctor have agreed that no other treatment gives sufficient seizure control for you.
- For epilepsy, you must not use Topiramate Capsules if you are a woman who is able to become pregnant unless you are using highly effective contraception. Do not stop taking Topiramate Capsules or your contraception (birth control) until you have discussed this with your doctor. Your doctor will make sure you have received information about the risks of taking Topiramate Capsules during pregnancy and about the risks of seizures during pregnancy, which may put you or your unborn child at risk.
- Before the start of treatment with Topiramate Capsules a pregnancy test should be performed in a woman who is able to become pregnant.

The risks of topiramate when taken during pregnancy. The risks apply whether topiramate is taken for migraine prevention or treatment of epilepsy

There is a risk of harm to the unborn child if Topiramate Capsules are used during pregnancy.

- If you take Topiramate Capsules during pregnancy, your child has a higher risk for birth defects. In women who take topiramate, around 4-9 children in every 100 will have birth defects. This compares to 1-3 children in every 100 born to women who do not have epilepsy and do not take an antiepileptic treatment. Particularly, cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth) have been observed. 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.
- If you take Topiramate Capsules during pregnancy, your child may have a 2- to 3-fold higher risk for autism spectrum disorders, intellectual disabilities, or attention deficit hyperactivity disorder (ADHD) compared with children born to women with epilepsy not taking antiepileptic medication.
- If you take Topiramate Capsules during pregnancy, your child may be smaller and weigh less than expected at birth. In one study, around 18 in every 100 children of mothers taking topiramate during pregnancy were smaller and weighed less than expected at birth, while around 5 in every 100 children born to women without epilepsy and not taking antiepileptic medication were smaller and weighed less 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.

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Need for contraception (birth control) in women who are able to become pregnant

- If you are a woman who is able to become pregnant, talk to your doctor about other possible treatments instead of Topiramate Capsules. If the decision is made to use Topiramate Capsules, you must use highly effective contraception during your treatment and for at least 4 weeks after the last Topiramate Capsules dose.
- One highly effective contraception (such as an intrauterine device) or two complementary contraceptives such as birth control pill together with a barrier method of birth control (such as a condom or pessary/diaphragm) must be used. Talk to your doctor about what contraception is most appropriate for you.
- Topiramate Capsules can affect how well some hormonal contraceptive (birth control) methods work. If you are taking hormonal contraceptives, an additional barrier contraceptive method (such as a condom or pessary/diaphragm) should be used.
- Tell your doctor if you experience irregular menstrual bleeding.

Use of Topiramate Capsules in girls

If you are a parent or a caregiver of a girl treated with Topiramate Capsules, you must contact her doctor immediately once your child experiences her first period (menarche). The doctor will inform you about the risks to an unborn child due to topiramate exposure during pregnancy, and the need for using highly effective contraception.

If you wish to become pregnant while taking Topiramate Capsules

- Schedule an appointment with your doctor.
- Do not stop using your contraception until you have discussed this with your doctor.
- If you take Topiramate Capsules for epilepsy, do not stop taking it until you have discussed this with your doctor. Suddenly stopping Topiramate Capsules can cause seizures to start again or happen more often or last longer than before. This may put you or your unborn child at risk.
- Your doctor will reassess your treatment as they may need to change or stop your medicine. Your doctor will counsel you about the risks of Topiramate Capsules during pregnancy. They may also refer you to another specialist.

If you have become pregnant or think you may be pregnant while taking Topiramate Capsules

- Schedule an urgent appointment with your doctor.
- If you are taking Topiramate Capsules to prevent migraine, stop taking the medicine straight away, and contact your doctor. Your doctor will assess your condition and discuss your options with you.
- If you are taking Topiramate Capsules for epilepsy, do not stop taking this medicine unless your doctor tells you to. Suddenly stopping Topiramate Capsules can cause seizures to start again or happen more often or last longer than before. This may put you or your unborn child at risk.
- If you are taking Topiramate Capsules for epilepsy, your doctor will assess your condition and discuss options with you. Your doctor will make sure you are aware of and understand all the risks of Topiramate Capsules during pregnancy. They may advise that you need to switch to another medicine to treat your epilepsy. If so, they will explain how to make the change to this new medicine. They may also refer you to another specialist.
- If Topiramate Capsules are used during pregnancy for epilepsy, you will be monitored closely to check how your unborn child is developing.

Make sure you read the patient guide that you will receive from your doctor.

A patient card is provided with the Topiramate Capsules package to remind you of topiramate risks in pregnancy.

Breast-feeding

The active substance in Topiramate Capsules (topiramate) passes into breast milk. Effects have been seen in breast-fed 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 Capsules. 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.

Continued on next page

Topiramate Capsules contain sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

This medicine contains less than 1 mmol sodium (23mg) per hard capsule, that is to say essentially sodium-free.

3. HOW TO TAKE TOPIRAMATE CAPSULES

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 Capsules may be swallowed whole or may be opened and sprinkled on a teaspoon of soft food of any type. Examples are apple sauce, custard, ice cream, porridge, pudding or yoghurt. Drink fluids right after to make sure all of the food and medicine mixture is swallowed.
- Hold the hard capsule upright so that the wording is the correct way up.
- Carefully twist off the top part (cap) of the capsule. You may find it best to do this over the small portion of food onto which you will be pouring the sprinkles.
- Sprinkle all of the capsule's contents onto a spoonful of soft food, taking care to see that the entire prescribed dosage is sprinkled onto the food.
- Be sure to swallow the entire spoonful of the sprinkle/food mixture immediately. Avoid chewing.
- Drink fluids immediately in order to make sure all of the mixture is swallowed.
- Never store any medicine and food mixture for use at a later time.
- Topiramate Capsules 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 Capsules 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, have abdominal pain or seizures (fits).

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

If you forget to take Topiramate Capsules

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 Capsules

Do not stop taking Topiramate Capsules 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 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):

- 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, excess calcium deposits in kidneys, 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)
- Decrease in platelets (blood cells that help stop bleeding), decrease in

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potassium level in the blood

- 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
- Hearing, seeing, or feeling things that are not there, severe mental disorder (psychosis)
- Fainting
- Pancreatitis (inflammation of the pancreas)
- Loss of part of the field of vision
- Loss of hearing.

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

- Severe skin reactions, including Stevens-Johnson syndrome (a potentially life-threatening skin condition that may present with sores in multiple mucosal sites (such as the mouth, nose or eyes), a skin rash or blistering) and erythema multiforme (a condition of raised red spots that can blister)
- 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 (hyperammonaemia), which can lead to a change in brain function (hyperammonaemic encephalopathy)
- Reduced number of neutrophils (a type of white blood cell)
- Inflammation of the liver, liver failure.

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

- 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

If any of the following side effects get serious, contact 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, nausea or dizziness
- Weight loss, diarrhoea.

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

- Anaemia (reduced number of red blood cells)
- 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
- Reduced sense of touch or sensation
- Involuntary trembling or shaking
- Visual disturbance, such as double vision, blurred vision, decreased vision, rapid or involuntary movements of the eyes
- 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, tingling or numbness of the mouth
- Hair loss
- Skin rash and/or itchy skin
- Joint pain, muscle spasms or twitching, muscle aches or weakness, chest pain
- Weight gain.

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

- Decrease in white blood cells that help to protect you against infection, decrease in bicarbonate 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, increased thirst and excessive intake of fluid

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Topiramate ▼ Pregnancy
Prevention Programme

Patient Card

▼ This medicinal product is subject to additional monitoring. Report any side effects to www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Important information for all patients who could become pregnant

Contraception and Pregnancy Prevention – Important information to know

- Topiramate is an effective medicine for epilepsy and prevention of migraine.
- Topiramate can seriously harm a baby when taken during pregnancy.
- **Use effective birth control (contraception) at all times** during your treatment with topiramate and for at least 4 weeks after the last dose.
- Discuss with your doctor about which method of birth control is most suitable for you.
- It is important to visit your doctor to review your treatment at least once each year.

What you must do

- Read the package leaflet carefully before use.
- Read the **Patient Guide** for the topiramate pregnancy prevention programme. You should have received a copy from your doctor, or it can be found online at www.medicines.org.uk by entering “topiramate” in the search box and then clicking on “Risk Materials”.
- If you are **thinking about having a baby**, make an appointment with your GP. Do not stop using topiramate and contraception before you have talked to your doctor.
- If you **think you are pregnant and are taking topiramate for epilepsy**, 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).
- If you **think you are pregnant and are taking topiramate for migraine prevention**, stop taking topiramate straight away and contact your GP.

**PRESCRIBING DOCTOR'S
NAME:**

**PRESCRIBING DOCTOR'S
PHONE NUMBER:**
