

Package leaflet: Information for the user

Topiramate Morningside 25 mg film-coated tablets
Topiramate Morningside 50 mg film-coated tablets
Topiramate Morningside 100 mg film-coated tablets
Topiramate Morningside 200 mg film-coated tablets

Topiramate

▼ 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 Morningside is and what it is used for
2. What you need to know before you take - Topiramate Morningside
3. How to take -Topiramate Morningside
4. Possible side effects
5. How to store -Topiramate Morningside
6. Contents of the pack and other information

1. What Topiramate Morningside is and what it is 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 Morningside

Do not take Topiramate Morningside

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 Morningside if you are pregnant.

- If you are a woman who is able to become pregnant, you must not take Topiramate Morningside, 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 Morningside 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 Morningside unless you use highly effective contraception (birth control) during your treatment. The only exception is if Topiramate Morningside is the only treatment giving you sufficient seizure control and you are planning to become pregnant. You must speak to your doctor to make sure you have received information about the risks of taking Topiramate Morningside 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 or scan the QR-code for it (see section 6 ‘Other sources of information’).

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

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Topiramate Morningside 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 Morningside 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 Morningside dose. See section ‘pregnancy and breastfeeding’ for further information.
- are pregnant. Topiramate Morningside can harm an unborn child when taken during pregnancy.

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

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 Morningside.

You may lose weight if you use Topiramate Morningside 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.

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

Other medicines and Topiramate Morningside

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Topiramate Morningside and certain other medicines can affect each other. Sometimes the dose of some of your other medicines or Topiramate Morningside 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).
- hormonal contraceptives. Topiramate Morningside may make hormonal contraceptives less effective. 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 Morningside.

Tell your doctor if your menstrual bleeding changes while you are taking hormonal contraceptives and Topiramate Morningside. 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 and 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, flunarazine, 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 Morningside.

Topiramate Morningside with food and drink

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

Pregnancy, and breast-feeding and fertility

Important advice for women who are able to become pregnant

Topiramate Morningside 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 Morningside if you are pregnant.
- For migraine, you must not use Topiramate Morningside if you are a woman who is able to become pregnant unless you are using highly effective contraception.
- Before the start of treatment with Topiramate Morningside 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 Morningside if you are pregnant, unless no other treatment gives sufficient seizure control for you.
- For epilepsy, you must not use Topiramate Morningside if you are a woman who is able to become pregnant unless you are using highly effective contraception. The only exception is if Topiramate Morningside is the only treatment giving you sufficient seizure control, and you are planning to become pregnant. You must speak to your doctor to make sure you have received information about the risks of taking Topiramate Morningside 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 Morningside a pregnancy test should be performed in a woman who is able to become pregnant.

The risks of topiramate when taken during pregnancy (irrespective of the disease for which topiramate is used):

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

- If you take Topiramate Morningside 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 Morningside 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 Morningside during pregnancy, your child may be smaller and weigh less than expected at birth. In one study, 18 % of children of mothers taking topiramate during pregnancy were smaller and weighed less than expected at birth, while 5 % of 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.

Need for contraception 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 Morningside. If the decision is made to use Topiramate Morningside, you must use highly effective contraception during your treatment and for at least 4 weeks after the last Topiramate Morningside 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.
- If you are taking hormonal contraceptives, there is the possibility of reduced effectiveness of the hormonal contraceptive due to topiramate. Therefore, 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 Morningside in girls:

If you are a parent or a caregiver of a girl treated with Topiramate Morningside, 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 Morningside:

- Schedule an appointment with your doctor.

- Do not stop using your contraception until you have discussed this with your doctor.
- If you take Topiramate Morningside for epilepsy, do not stop taking it until you have discussed this with your doctor because your illness may become worse.
- Your doctor will reassess your treatment and evaluate alternative treatment options. The doctor will counsel you about the risks of Topiramate Morningside during pregnancy. He/she may also refer you to another specialist.

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

- Schedule an urgent appointment with your doctor.
- If you are taking Topiramate Morningside to prevent migraine, stop taking the medicine straight away, and contact your doctor to evaluate if you need alternative treatment.
- If you are taking Topiramate Morningside for epilepsy, do not stop taking this medicine until you have discussed this with your doctor, as this may worsen your illness. Worsening of your epilepsy may put you or your unborn child at risk.
- Your doctor will reassess your treatment and evaluate alternative treatment options. The doctor will counsel you about the risks of Topiramate Morningside during pregnancy. He/she may also refer you to another specialist.
- If Topiramate Morningside is used during pregnancy, 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. The patient guide is also available by scanning a QR code, see section 6 ‘Other sources of information’. A patient card is provided with the Topiramate Morningside package to remind you of topiramate risks in pregnancy.

Breast-feeding

The active substance in Topiramate Morningside (topiramate) passes into human milk. Effects have been seen in breastfed babies of treated mothers, including diarrhea, feeling sleepy, feeling irritable, and poor weight gain. Therefore, your doctor will discuss with you whether you abstain from breastfeeding or whether to abstain from treatment with Topiramate Morningside. Your doctor will take into account the importance of the medicine to the mother and the risk for the baby.

Mothers who breastfeed while taking Topiramate Morningside 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 Morningside contains lactose

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

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

3. How to take Topiramate Morningside

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Girls and women who are able to become pregnant:

Topiramate Morningside treatment should be started and supervised by a doctor experienced in the treatment of epilepsy or migraine. Visit your doctor to review your treatment at least once a year.

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

If you take more Topiramate Morningside 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 Morningside.

If you forget to take Topiramate Morningside

- 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 Morningside

Do not stop taking this medicine unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop this medication, your dose may be decreased gradually over a few days.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor, or seek medical attention immediately if you have the following side effects:

Very common (may affect more than 1 in 10 people)

– Depression (new or worse)

Common (may affect up to 1 in 10 people)

– Seizures (fits)

– Anxiety, irritability, changes in mood, confusion, disorientation

– Problems with concentration, slowness of thinking, loss of memory, problems with memory (new onset, sudden change or increased severity)

– Kidney stone, frequent or painful urination

Uncommon (may affect up to 1 in 100 people)

– Increased acid level in the blood (may cause troubled breathing including shortness of breath, loss of appetite, nausea, vomiting, excessive tiredness, and fast or uneven heart beats)

– Decreased or loss of sweating (particularly in young children who are exposed to high temperatures)

– Having thoughts of serious self-harm, trying to cause serious self-harm

– Loss of part of the field of vision

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

– Glaucoma – blockage of fluid in eye causing increased pressure in the eye, pain, or decreased vision

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

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

– Inflammation of the eye (uveitis) with symptoms such as eye redness, pain, sensitivity to light, runny eyes, seeing small dots or getting blurred vision.

Other side effects include the following, if they get serious, please tell your doctor or pharmacist:

Very common (may affect more than 1 in 10 people)

– Stuffy, runny nose or sore throat

– Tingling, pain and/or numbness of various body parts

– Sleepiness, tiredness

– Dizziness

– Nausea, diarrhoea

– Weight loss

Common (may affect up to 1 in 10 people)

– Anaemia (low blood count)

– Allergic reaction (such as skin rash, redness, itching, facial swelling, hives)

– Loss of appetite, decreased appetite

– Aggression, agitation, anger, abnormal behaviour

– Difficulty falling or staying asleep

– Problems with speech or speech disorder, slurred speech

– Clumsiness or lack of coordination, feeling of unsteadiness when walking

- Decreased ability to complete routine tasks
- Decreased, loss of, or no sense of taste
- Involuntary trembling or shaking; rapid, uncontrollable movements of the eyes
- Visual disturbance, such as double vision, blurred vision, decreased vision, difficulty focusing
- Sensation of spinning (vertigo), ringing in the ears, ear pain
- Shortness of breath
- Cough
- Nose bleeds
- Fever, not feeling well, weakness
- Vomiting, constipation, abdominal pain or discomfort, indigestion, stomach or intestinal infection
- Dry mouth
- Hair loss
- Itching
- Joint pain or swelling, muscle spasms or twitching, muscle aches or weakness, chest pain
- Weight gain

Uncommon (may affect up to 1 in 100 people)

- Decrease in platelets (blood cells that help stop bleeding), decrease in white blood cells that help to protect you against infection, decrease in potassium level in the blood
- Increase in liver enzymes, increase in eosinophils (a type of white blood cell) in the blood
- Swollen glands in the neck, armpit, or groin
- Increased appetite
- Elevated mood
- Hearing, seeing, or feeling things that are not there, severe mental disorder (psychosis)
- Showing and/or feeling no emotion, unusual suspiciousness, panic attack
- Problems with reading, speech disorder, problems with handwriting
- Restlessness, hyperactivity
- Slowed thinking, decreased wakefulness or alertness
- Reduced or slow body movements, involuntary abnormal or repetitive muscle movements
- Fainting
- Abnormal sense of touch; impaired sense of touch
- Impaired, distorted, or no sense of smell
- Unusual feeling or sensation that may precede a migraine or a certain type of seizure
- Dry eye, sensitivity of the eyes to light, eyelid twitching, watery eyes
- Decreased or loss of hearing, loss of hearing in one ear
- Slow or irregular heartbeat, feeling your heart beating in your chest
- Low blood pressure, low blood pressure upon standing (consequently, some people taking topiramate may feel faint, dizzy, or may pass out when they stand up or sit up suddenly)
- Flushing, feeling warm
- Pancreatitis (inflammation of the pancreas)
- Excessive passing of gas or wind, heartburn, abdominal fullness or bloating
- Bleeding gums, increased saliva, drooling, breath odour
- Excessive intake of fluids, thirst
- Skin discolouration
- Muscle stiffness, pain in side
- Blood in urine, incontinence (lack of control) of urine, urgent desire to urinate, flank or kidney pain
- Difficulty getting or keeping an erection, sexual dysfunction
- Flu-like symptoms
- Cold fingers and toes

- Feeling drunk
- Learning disability

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

- Abnormally elevated mood
- Loss of consciousness
- Blindness in one eye, temporary blindness, night blindness
- Lazy eye
- Swelling in and around the eyes
- Numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to the cold
- Inflammation of the liver, liver failure
- 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
- Abnormal skin odour
- Discomfort in your arms or legs
- Kidney disorder
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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 should call your doctor if you notice a change or decrease in your vision.
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- 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
- Diffi culty 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 Yellow Card Scheme: 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 Morningside

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.

This medical product does not require any special precautions for storage.

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 Morningside contains

Topiramate Morningside 25 mg Film-coated tablets

- The active substance(s) is topiramate. Each film-coated tablet contains 25 mg topiramate.
- The other ingredients are (tablet nucleus): lactose monohydrate, pregelatinized maize starch, sodium starch glycolate (Type A), microcrystalline cellulose, magnesium stearate and (tablet coating) basic butylated methacrylate copolymer, sodium laurilsulfate, magnesium stearate, stearic acid, talc and titanium dioxide (E171).

Topiramate Morningside 50 mg Film-coated tablets

- The active substance(s) is topiramate. Each film-coated tablet contains 50 mg topiramate.
- The other ingredients are (tablet nucleus): lactose monohydrate, pregelatinized maize starch, sodium starch glycolate (Type A), microcrystalline cellulose, magnesium stearate and (tablet coating) basic butylated methacrylate copolymer, sodium laurilsulfate, magnesium stearate, stearic acid, talc, titanium dioxide (E171) and yellow iron oxide (E172).

Topiramate Morningside 100 mg Film-coated tablets

- The active substance(s) is topiramate. Each film-coated tablet contains 100 mg topiramate.
- The other ingredients are (tablet nucleus): lactose monohydrate, pregelatinized maize starch, sodium starch glycolate (Type A), microcrystalline cellulose, magnesium stearate and (tablet coating) basic butylated methacrylate copolymer, sodium laurilsulfate, magnesium stearate, stearic acid, talc, titanium dioxide (E171) and yellow iron oxide (E172).

Topiramate Morningside 200 mg Film-coated tablets

- The active substance(s) is topiramate. Each film-coated tablet contains 200 mg topiramate.
- The other ingredients are (tablet nucleus): lactose monohydrate, pregelatinized maize starch, sodium starch glycolate (Type A), microcrystalline cellulose, magnesium stearate and (tablet coating) basic butylated methacrylate copolymer, sodium laurilsulfate, magnesium stearate, stearic acid, talc, titanium dioxide (E171) and iron oxide (E172).

What Topiramate Morningside looks like and contents of the pack

Topiramate Morningside is available as film coated tablet.

Topiramate Morningside 25 mg Film-coated tablets

Topiramate Morningside 25 mg Film-coated tablets are white, round and convex

Topiramate Morningside 50 mg Film-coated tablets

Topiramate Morningside 50 mg Film-coated tablets are yellow, round and convex.

Topiramate Morningside 100 mg Film-coated tablets

Topiramate Morningside 100 mg Film-coated tablets are yellow, round and convex.

Topiramate Morningside 200 mg Film-coated tablets

Topiramate Morningside 200 mg Film-coated tablets are yellow, round and convex.

Topiramate Morningside is available in packages with 10 and 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Morningside Healthcare Ltd

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Leicester, LE19 1WP, UK

Manufacturers

Atlantic Pharma – Produções Farmacêuticas, S.A.

Rua da Tapada Grande, n.º 2, Abrunheira, 2710-089 Sintra, Portugal

This medicinal product is authorised in the Member States of the EEA under the following names:

Italy: Xitop

Greece: JADIX[®] 25, 50, 100, 200 mg επικαλυμμένα με λεπτό υμένιο δισκία

Portugal: Topiramato Clindonim

United Kingdom: Topiramate Morningside 25, 50, 100, 200 mg Film-coated tablets

This leaflet was last revised in December 2023.

Other sources of information

Latest approved information product information, educational material on this medicine is available by scanning the following QR code with a smartphone. The same information is also available on the following website (URL):
{URL to be printed on the mock-up}

QR code printed here during mock-up creation.