

PRADOX 25MG FILM COATED TABLET

PRADOX 50MG FILM COATED TABLET

PRADOX 100MG FILM COATED TABLET

Topiramate (25 mg, 50 mg, 100 mg)

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What Pradox is used for

Pradox belongs to a group of medicines called 'antiepileptic medicines'. It is used:

- alone to treat seizures in adults
- with other medicines to treat seizures in adults and children aged 2 years and above
- to prevent migraine headaches in adults

Your doctor may have prescribed Pradox for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

How Pradox works

Although the exact way Pradox works is unknown, it's believed to help 'calm' overexcitable nerve cells in the brain so they don't send out the signals that can cause migraines or seizures.

Before you take Pradox

- When you must not use it

- if you are allergic (hypersensitive) to Topiramate or any of the other ingredients of Pradox (listed in section '*Ingredients*')
- for migraine prevention: if you are pregnant or if you are a woman of childbearing potential unless you are using effective contraception. You should talk to your doctor about the best kind of contraception to use while you are taking Pradox.

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

Pregnancy and breastfeeding

Migraine prevention:

Pradox can harm an unborn baby. You must not use Pradox if you are pregnant. You must not use Pradox 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 Pradox is suitable for you. Before the start of treatment with Pradox a pregnancy test should be performed.

Treatment of epilepsy:

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

As with other antiepileptic medicines, there is a risk of harm to the unborn child if Pradox is used during pregnancy. Make sure you are very clear about the risks and the benefits of using Pradox during pregnancy.

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

you will continue to take Pradox while you are pregnant.

- It is important that you do not stop taking your medicine without first consulting your doctor.
- You should talk to your doctor about the best kind of birth control to use while you are taking Pradox. You should use effective contraception. Before the start of treatment with Pradox, a pregnancy test should be performed. Talk to your doctor if you wish to become pregnant.

Breastfeeding

The active substance in Pradox (Topiramate) passes into breast 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 Pradox. 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 Pradox must tell the doctors as soon as possible if the baby experiences anything unusual.

- Before you start to use it

Talk to your doctor or pharmacist before taking Pradox 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 taking Pradox to treat epilepsy and you are pregnant or a woman of childbearing potential (see section '*Pregnancy and Breastfeeding*' for further information)

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

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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 Pradox.

You may lose weight if you use Pradox your weight should be checked regularly when using this medicine. If you are losing too much weight or a child using this medicine is not gaining enough weight, you should consult your doctor.

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

Pradox 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 'Side effects')

- difficulty thinking, remembering information, or solving problems
- being less alert or aware
- feeling very sleepy with low energy

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

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

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

Keep a list of all 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 includes:

- antiepileptic medicines
- Risperidone, Lithium (used as antipsychotics)
- Hydrochlorothiazide, Propranolol (used to treat high blood pressure)
- Metformin, Pioglitazone, Glyburide (used to treat diabetes)
- Amitriptylline, Diltiazem (used to treat heart conditions)
- Flunarizine (used to treat migraines)

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

How to take Pradox

- How much to take

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

Epilepsy – adjunctive therapy

Adults

25 to 50mg nightly for one week. Subsequently at weekly or bi-weekly intervals, dose should be increased by 25 to 50 to 100mg/day and taken in two divided doses.

Children aged 2 and above

5 to 9 mg/kg/day in two divided doses. Titration should begin at 25 mg (or less, based on a range of 1 to 3 mg/kg/day) nightly for the first week. The dosage should then be increased at 1 or 2-weekly intervals by increments of 1 to 3 mg/kg/day, to achieve optimal clinical response.

Epilepsy - monotherapy

Adults

Titration should begin at 25 mg nightly for 1 week. The dosage should then be increased at 1- or 2-week intervals by

increments of 25 or 50 mg/day, administered in two divided doses. The recommended initial target dose for Topiramate monotherapy in adults is 100 mg/day and the maximum recommended daily dose is 500 mg. Some patients with refractory forms of epilepsy have tolerated Topiramate monotherapy at doses of 1000 mg/day.

Children aged 2 and above

Begin at 0.5 to 1 mg/kg nightly for the first week. The dosage should be increased at 1 or 2-weekly intervals by increments of 0.5 mg/Kg/day to 1 mg/Kg/day, administered in two divided doses.

The recommended initial target dose range for Topiramate monotherapy in children aged two years and above is 3 to 6 mg/kg/day. Children with recently diagnosed partial onset seizures have received doses of up to 500 mg/day.

Migraine

Adults

100 mg/day in two divided doses beginning with 25mg nightly for 1 week. Dosage should be then increased in increments of 25mg/day at 1 week intervals.

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

Pradox is to be swallowed whole. Avoid chewing the tablets as they may leave a bitter taste.

Pradox can be taken before, during, or after a meal. Drink plenty of fluids during the day to prevent kidney stones while taking Pradox.

- When to take it

Use as directed by your doctor or pharmacist.

- How long to take it

Continue taking Pradox for as long as your doctor recommends.

- If you forget to take it

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,

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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 take too much (overdose)

- 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 Pradox.

While you are taking Pradox

- Things you must do

- Drink plenty of water. Pradox has been known to cause kidney stones and drinking water may help prevent this.
- Always follow your doctor's instruction carefully.
- If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking Pradox.
- Tell your doctor if you become pregnant while taking Pradox.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not drink alcohol.
- Do not take any new medicines without consulting your doctor.
- Do not give Pradox to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Effects on thoughts and behavior

Medicines used to treat epilepsy can increase the risk of suicidal thoughts and behavior. If you experience feeling of deep sadness and unworthiness (depression) or a worsening of these feelings, any unusual changes in your mood or the emergence of suicidal thoughts, behavior or thoughts of self-harm, you should report this to your doctor immediately.

Driving and using machines

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

Side effects

Like all medicines, Pradox 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)
- Stuffy, runny nose or sore throat
- Tingling, pain and/or numbness of various body parts
- Sleepiness, tiredness
- Dizziness
- Nausea, diarrhea
- Weight loss

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
- Anemia (low blood count)
- Allergic reaction (such as skin rash, redness, itching, facial swelling, hives)
- Loss of appetite, decreased appetite
- Aggression, agitation, anger, abnormal behavior
- 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

Unknown

- Sudden changes in your eyesight (e.g blurred vision)
- Eye pain
- Red eye

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 behavior
- 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

There is a potential significant risk for metabolic acidosis that may have no

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symptoms and if left untreated may be associated with adverse effects on kidneys (e.g. kidney stone/nephrocalcinosis)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Pradox

- *Storage*

Keep medicines out of sight and reach of children.

Do not use Pradox after the expiry date.

Store at temperature of not more than 30°C. Protected from moisture. Store in the original package.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will you protect the environment.

Product Description

- *What it looks like?*

25 mg: White, round, biconvex, film coated tablet with engraved T on one side and 25 on the other

50 mg: Pale yellow, round, biconvex, film coated tablet with engraved T on one side and 50 on the other

100 mg: Yellow, round, biconvex, film coated tablet with engraved T on one side and 100 on the other

- *Ingredients*

- *Active ingredient:*

Topiramate (25 mg, 50 mg, and 100 mg)

- *Inactive ingredients:*

Microcrystalline cellulose (Avicel PH 101), Dibasic sodium phosphate anhydrous, Croscarmellose sodium, Crospovidone (Crospovidone XL-10), Poloxamer (Lutrol F 68), Sodium lauryl sulfate, Talc, Hydroxypropyl cellulose (Klucel LF), Povidone (PVP K-90), Polysorbate 80 (Tween 80), Butylated hydroxytoluene, Isopropyl alcohol, Magnesium aluminometasilicate (Neusilin UFL2), Polyethylene glycol (PEG 6000), Colloidal silicon dioxide (Aerosil 200), Magnesium stearate, Hypromellose (HPMC 2910), Titanium dioxide, Iron oxide yellow (C.I. No. 77492) [50 mg and 100 mg], Polyethylene glycol (PEG 400), Methylene chloride, and Purified water

- *MAL Number: -*

25mg: MAL23096014AZ

50mg: MAL23096015AZ

100mg: MAL23096016AZ

Manufacturer

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Product Registration Holder

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