

Assessed against UK PIL dated July 2005

**TOPAMAX 25mg TABLETS
TOPAMAX 50mg TABLETS
TOPAMAX 100mg TABLETS
(topiramate)**

APPROVED
By cilgit at 2:21 pm, 10/12/05

Final Draft

This product is available using any of the above names, but will be referred to as Topamax Tablets throughout this:

Patient Information Leaflet

Please read this information carefully before you start to take your medicine. It contains all the information you should need to know. If you have any questions or are not sure about anything, ask your doctor or pharmacist. Keep this leaflet whilst you are taking this medicine, you may wish to refer to it again.

ABOUT YOUR MEDICINE:

Your medicine is called Topamax Tablets.

What is your medicine made of?

The active ingredient is topiramate. Your medicine is available as Tablets containing either 25, 50, or 100mg of topiramate

Topamax Tablets also contains the following inactive ingredients: lactose monohydrate, pregelatinized maize starch, microcrystalline cellulose, sodium starch glycollate, magnesium stearate, carnauba wax, hypromellose, titanium dioxide (E171), macrogol, and polysorbate 80. The 50mg and 100mg tablets also contain iron oxide (E172).

Your medicine contains lactose. If your doctor has told you that you have intolerance to some sugars contact your doctor before taking this medicinal product.

What should your medicine look like?

Topamax 25mg Tablets are round, white film-coated tablets marked 'TOP' on one side and '25' on the reverse.

Topamax 50mg Tablets are round, light-yellow film-coated tablets marked 'TOP' on one side and '50' on the reverse.

Topamax 100mg Tablets are round, yellow film-coated tablets marked 'TOP' on one side and '100' on the reverse.

Topamax Tablets are available as blister packs of 60 tablets.

What type of medicine are Topamax Tablets?

Topamax Tablets affect chemicals in the brain that are involved in sending signals to the nerves. Topamax Tablets belong to a group of medicines used to treat epilepsy and may also be used to prevent migraine headaches. Topamax Tablets should be taken continuously to prevent frequently recurring migraine headaches.

Topamax 25mg Tablets	PL 10383/1203
Topamax 50mg Tablets	PL 10383/1204
Topamax 100mg Tablets	PL 10383/1205

POM

Your medicine is manufactured by Janssen-Cilag Pharmaceutica N.V., Turnhoutseweg 30, 2340 Beerse, Belgium. Procured from within the EU and repackaged by the Product Licence Holder: Primecrown Ltd, 28 Sarum Complex, Uxbridge, Middlesex, UB8 2RZ.

WHY YOU NEED TO TAKE THIS MEDICINE:

Epilepsy:

Topamax Tablets are used to treat various types of epilepsy.

Topamax Tablets may be used on its own to treat adults and children aged 6 years and over.

They can also be used in combination with other anti-epileptic medicines in both adults and children aged 2 years and over.

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Migraine:

Topamax Tablets are also used to prevent frequently recurring migraine headaches in adults and children over 16 years old. Treatment must be started under specialist care and continued under the supervision of a specialist. Topamax Tablets are not intended to treat an individual attack.

BEFORE YOU TAKE YOUR MEDICINE:

Make sure it is safe for you to take Topamax Tablets. **Do not** take these tablets if you are allergic to any of the ingredients in the product.

As when taking other medicines, you should tell your doctor if you

- are pregnant or think you might be pregnant or if you intend to become pregnant. Your doctor will then discuss with you if you should continue to take Topamax Tablets.
- are breast feeding. Your doctor may ask you to stop breast feeding as Topamax Tablets may reach your baby through your milk.
- have or have had kidney stones or kidney disease. Your doctor may want you to increase the amount of water you drink while you are taking this medicine.

Epilepsy:

Topamax Tablets should not usually be given to children under 2 years old.

Migraine:

Topamax Tablets have not been studied in children under 16 years old.

Are you taking other medicines?

Please tell your doctor about **all** medicines you are using, including those you bought without a prescription and any other remedies or dietary supplements such as vitamins.

It is especially important that your doctor knows if you are taking digoxin, hydrochlorothiazide, metformin, pioglitazone, contraceptive pills, amitriptyline, haloperidol, propranolol or other anti-epileptic drugs, such as phenytoin or carbamazepine.

Special Warnings:

- Topamax Tablets may cause you to be less alert than normal. Make sure you know how you are affected by this medicine before you drive, use machines or do anything else that could be dangerous if you are not alert.
- You should be careful how much alcohol you drink while taking Topamax Tablets, or if you are taking any medicines that make you sleepy or less alert (these include tranquillisers, anti-depressants and sleeping pills), as the combined effect might make you feel less alert than usual.
- If you are taking a contraceptive pill as well as Topamax Tablets and your menstrual bleeding patterns change (e.g. if you experience breakthrough bleeding, spotting or if you miss a period), consult your doctor.
- Your doctor should discuss with you the possible effects of Topamax Tablets on the unborn child and the risks should be weighed against the benefits of treatment with Topamax Tablets.
- It is important to drink plenty of water when taking Topamax Tablets especially if you are taking exercise or the weather is hot.
- If you, or a close relative, have ever had kidney stones, you have a greater risk for kidney stone formation which may cause acute pain in the flank (side of the abdomen) and Topamax Tablets may increase this risk.
- If you suffer from problems with your liver, please tell your doctor before taking Topamax Tablets. Your doctor may want to prescribe a lower dose.
- You may notice a change in your mood, or experience feelings of depression while taking Topamax Tablets.
- Rarely, patients taking Topamax Tablets can sometimes have thoughts of harming themselves or taking their own lives. If you get these thoughts at any time, **contact your doctor or go to a hospital straight away.**
- If you are losing too much weight or a child taking Topamax Tablets is not gaining enough weight the amount of food being eaten should be increased.

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- Rarely, sudden blurring of vision, pain and redness of the eyes has occurred, in both adults and children, typically during the first month of starting Topamax Tablets. This can indicate raised pressure within the eye (glaucoma). If you develop any eye symptoms, particularly in the first few weeks of treatment, you should tell your doctor immediately. If your doctor thinks you have raised pressure within the eye, he/she will advise you on how to stop taking Topamax Tablets and may refer you for specific eye treatment. You may also need to revisit your specialist to ensure your epilepsy is kept under control.
- Rarely, blood tests have shown a slight increase in acidity. Your doctor will monitor this, if necessary, and may adjust the amount of Topamax Tablets you are taking.
- You may experience significant and continuing weight loss while taking Topamax Tablets. You should therefore be weighed and monitored regularly.

HOW TO TAKE YOUR MEDICINE:

- Topamax Tablets should be taken continuously.
- It is important that you follow your doctor's instructions about when and how to take this medicine. The pharmacy label will tell you how much to take and how often. If it does not or you are not sure, ask your doctor or pharmacist.
- Topamax Tablets are taken twice a day. Take half the dose in the morning and half in the evening.
- Always swallow the tablets with plenty of water. You can take the tablets with or without food.

WHAT TO DO IF YOU MISS A DOSE:

If you miss a dose, take it as soon as you remember. But, if it is almost time for the next dose, do not take the missed dose and then carry on as before.

Do not suddenly stop taking this medicine without first checking with your doctor.

Always check you have enough tablets and do not run out.

Epilepsy:

Your doctor will start with a low dose and slowly increase the dose to the lowest amount needed to control your epilepsy.

If you are taking only Topamax Tablets to treat your epilepsy:

For adults and children over 16 years old, the usual dose is 100mg per day but your doctor may tell you to use a higher or lower dose.

For children aged 6 or over, the usual daily dose is 3 to 6 mg/kg/day. Your doctor will tell you how much to take.

If you are taking Topamax tablets and other anti-epileptic drugs:

For adults and children over 16 years old, the usual dose is 200 to 400 mg per day but your doctor may tell you to use a higher or lower dose.

For children aged between 2 and 16 years old, the usual daily dose is 5 to 9 mg/kg/day. Your doctor will tell you how much to take.

To prevent frequently recurring migraine headaches:

- If you suffer from frequently recurring migraine headaches, although you may not have a migraine headache every day, it is important that you follow your doctor's instructions carefully to help reduce the chance of getting a migraine headache.
- Your doctor will start treatment with a dose of 25 mg to be taken at night. Your doctor will then increase your dose to the lowest amount needed to prevent frequently recurring migraine headaches.
- For adults and children over 16 years old, the usual dose is 100 mg per day. Topamax Tablets are taken twice a day (50 mg morning and 50 mg at night). Your doctor may tell you to use a lower or higher dose. Your doctor will review your treatment every six months.
- Topamax Tablets are not recommended in children under 16 years to prevent migraine headaches.

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- If you are to stop taking this medicine for prevention of your frequently recurring migraine headaches, your doctor will reduce the dose of Topamax Tablets you are taking gradually, in order to avoid 'rebound' migraine headaches (sudden worsening of your migraine headaches).

WHAT TO DO IF AN OVERDOSE IS TAKEN:

If you accidentally take too many tablets, contact your doctor or nearest hospital casualty department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you to show the doctor what you have taken.

AFTER TAKING YOUR MEDICINE:

What side effects may Topamax Tablets cause?

As with any other medicine Topamax Tablets may some unwanted effects.

The most often reported side effects in children and adults being treated for epilepsy include: headaches, changes in thinking, including difficulty in concentrating, slow thinking, confusion and forgetfulness; dizziness, tiredness, drowsiness, tingling, mood swings, nervousness, anxiety, weakness, stomach pains, feeling sick, weight loss, loss of appetite, depression, difficulty sleeping, numbness and vision disorders.

Less frequently reported are: agitation, taste changes, kidney stones (that may present as blood in the urine or pain in the lower back or genital area), co-ordination problems, loss of emotional feeling, aggressive behaviour, a decrease in white blood cells, hallucinations and changes in thoughts, feelings or behaviour which may become confused.

In addition increased saliva in the mouth, changes in behaviour and an inability to keep still have also been reported in children.

The following side effects have been seen during clinical trials of Topamax in preventing frequently recurring migraine:

The most often reported effects were: tiredness, pins and needles in the fingers and toes, dizziness, lowered sense of feeling in the skin, difficulty with language, nausea, diarrhoea, indigestion, dry mouth, weight loss, decrease in appetite, drowsiness, forgetfulness, difficulty with concentration or attention, difficulty in sleeping (insomnia), anxiety, mood swings, depression, changes in taste and vision disorders. During the clinical trials, pins and needles in the fingers and toes was experienced by 50% of patients.

General:

Rarely, blood clots have occurred in patients given Topamax Tablets. However, it has not been proven that these were caused by this medicine. Rarely, blurring of vision and eye pain have been reported.

Rarely and mostly in children, reduced sweating has occurred, mainly during exercise or in particularly warm conditions. If someone taking Topamax Tablets becomes flushed or overheated, they should relax in a cool place and drink plenty of water.

Rarely, thoughts or attempts of committing suicide have been reported.

Very rarely, skin rashes, blisters on the skin and sore mouth/eyes have been reported. If you have a high temperature or feel unwell with one of these reactions, contact your doctor immediately.

A few baby boys have been reported with a minor change to the opening at the end of the penis after their mothers took Topamax Tablets while pregnant. However, it has not been proven that this was caused by Topamax Tablets.

Changes in the blood tests, which show how your liver is working, have been seen in patients taking Topamax Tablets with or without other medicines. Very rarely patients have had liver problems and liver failure when taking many medicines with Topamax Tablets.

Rarely, blood tests have shown a slight increase in acidity.

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If any of the above side effects occur and become troublesome, frequent and/or more severe, please consult your doctor for advice.

Tell your doctor or pharmacist if you notice any other unwanted effect not mentioned above.

STORING YOUR MEDICINE:

Do not use after the expiry date printed on the carton, label or blister strip.

Do not store above 25°C. Store in a dry place.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

If your doctor tells you to stop taking the tablets, please take them back to the pharmacist for safe disposal. Only keep them if your doctor tells you to.

If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

IMPORTANT:

This medicine is for YOUR use only. A doctor can only prescribe it. Never give it to anyone else. It may harm them even if their symptoms are the same as yours.

Tell medical staff you are taking Topamax Tablets for example if you go into hospital, or see a dentist or doctor.

This leaflet does not contain complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who has access to additional information.

Leaflet date: 10.08.2005