Topamax® SPRINKLE 25mg CAPSULES (topiramate)

Your medicine is known as Topamax Sprinkle 25mg Capsules but will be referred to as Topamax throughout the following leaflet. Information for other strengths of Topamax also may be present in this leaflet.

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

1. WHAT TOPAMAX IS AND WHAT IT IS USED FOR

Topamax belongs to a group of medicines called "antiepileptic 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 TOPAMAX

Do not take Topamax
• if you are allergic to topiramate or any of the other ingredients (see section 4 "Ingredients"
• for migraine prevention if you are pregnant, or you are able to become pregnant but you are not using effective contraception (see section 'pregnancy and breast-feeding' for further information)
• if you are not sure if the above applies to you, talk to your doctor or pharmacist before using Topamax.

Warnings and precautions
Talk to your doctor or pharmacist before taking Topamax 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 pregnant or could become pregnant (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 using Topamax.

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

3. HOW TO TAKE TOPAMAX

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 Topamax and increase your dose until the best dose is found for you
• Topamax hard capsules may be swallowed whole or may be opened and the matching capsules' contents added to a teaspoon of soft food or an adult beverage. Examples are applesauce, custard, ice cream, porridge, pudding or yogurt. Drink fluids right after to make sure all of the food or medicine mixture is swallowed
• Hold the hard capsule upright so that you can read the writing on top
• Carefully twist off the clear portion 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 sprinkles/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
• Topamax can be taken, before, during or after a meal. Drink plenty of fluids during the day to prevent kidney stones while taking Topamax

If you take more Topamax than you should
• See a doctor right away. Take the medicine pack with you
• You may feel sleepy, tired or less alert; 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).

Other medicine can happen if you are taking other medicines together with Topamax.

If you forget to take Topamax
• If you forget to take your 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 Topamax

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 medicine, 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:

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, disinhibition
• Problems with concentration, slowness of thinking, loss of memory, and change in mood 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 acidity in the blood may cause troubled breathing including shortness of breath, loss of appetite, nausea, vomiting, excessive thirst, 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

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

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 for advice before taking this medicine.

Your doctor will discuss use of contraceptives with you. as well as discussing whether Topamax is suitable for you. As with other anti-epileptic medicines, there is a risk of harm to the unborn child if Topamax is used during pregnancy. Make sure you are very clear about the risks and the benefits of using Topamax for epilepsy during pregnancy.

You should not take Topamax for migraine prevention if you are pregnant or you are able to become pregnant and you are not using effective contraception.

Mothers who breast feed while taking Topamax 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 Topamax. Do not drive or use any tools or machines without talking to your doctor first.

Topamax contains sucrlose
If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicinal product.
Rare (may affect up to 1 in 1,000 people)
- Glaucous – blockage of fluid in eye causing increased pressure in the eye, pain, or decreased vision

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

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

Other side effects include the following, if they get serious, many people taking Topamax may feel faint, dizziness, or may pass out when they stand up or sit up suddenly (consequently, some people taking Topamax 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, right blindness
- Lazy eye
- Swelling in and around the eyes
- Numbers, tingling and colour change (white, blue than 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 skin rashes 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

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 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
Other side effects that may occur in children are:

Common (may affect up to 1 in 10 people)
- Sensation of spinning (vertigo)
- Vomiting
- Fever
- Faint

Uncommon (may affect up to 1 in 100 people)
- Increased in eosinophils (a type of white blood cell in the blood)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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.medicines.org.uk/yellowcard

By reporting side effects, you can help provide more information on the safety of this medicine.

5 HOW TO STORE TOPAMAX

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not use Topamax after the expiry date which is stated on the carton and bottle label. The expiry date refers to the last day of that month.
- Capsules should not be thrown in your bin or put down the drain. If they are out of date, or no longer suitable for you, return them to your pharmacist.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Do not store your capsules above 25°C.
- Keep the bottle tightly closed.

6 CONTENTS OF THE PACK AND OTHER INFORMATION

What Topamax contains
- Each Topamax Sprinkle 25mg Capsule contains 25mg of the active ingredient, topiramate.
- Topamax also contains the following inactive ingredients: sugar spheres, povidone, cellulose acetate, gelatin, titanium dioxide (E171) and Opadex S-1-17720 ink.

What Topamax looks like and contents of the pack
Each Topamax Sprinkle 25mg capsule is in an opaque white capsule, impregnated 25mg in black and clear cap impregnated TOP in black ink. The capsule contains white spheres. Topamax is available in white plastic bottles with a tamper evident screw cap containing 20 or 60 capsules.

Product Licence holder
Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Charnilles House, Abarton Lane, Wembley, HA0 1DX.

Manufacturer
This product is manufactured by Janssen-Cilag, S.p.A., 04010 Bergo S. Michele, Latina, Italy.

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