

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

SENCRESUS 25 Film-Coated Tablets

SENCRESUS 50 Film-Coated Tablets

SENCRESUS 100 Film-Coated Tablets

SENCRESUS 200 Film-Coated Tablets

Topiramate

Read all of this leaflet carefully before you start taking

SENCRESUS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- SENCRESUS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What SENCRESUS is and what it is used for

SENCRESUS belongs to a group of medicines called Anticonvulsants including “anti-epileptic medicines”.

SENCRESUS is used with or without other medicines to treat epilepsy (seizures) in adults and children over 12 years of age.

2. What you need to know before you take SENCRESUS

Do NOT take SENCRESUS:

- If you are allergic to the active ingredient topiramate or any of the other ingredients (listed in section 6).
- If you are pregnant or planning to become pregnant unless the conditions of the Pregnancy Prevention Programme are fulfilled.
- If you are breast-feeding
- Parents must not give SENCRESUS tablets to children of younger than 12 years old
- If you are not sure if the above applies to you, talk to your doctor or pharmacist before using SENCRESUS.

Warnings and precautions

Take special care with SENCRESUS:

Discuss with your doctor or pharmacist before taking SENCRESUS if you:

- Have eye problems as your vision could be affected and you could experience pain in your eyes.
- Have breakthrough bleeding when you are using oral contraceptives and start taking SENCRESUS because the efficacy of the contraception can be decreased.

- Have liver disease as the clearance of SENCRESUS from the body may be decreased
- Have kidney disease or if you are on dialysis
- Have a history of body fluid disorders such as decreased serum bicarbonate because of kidney disease. It is important that you drink plenty of fluid while you are using SENCRESUS and your doctor should monitor your serum bicarbonate levels
- Are a woman who is at child-bearing age (able to become pregnant). SENCRESUS can cause harm to an unborn child if taken during pregnancy. Highly effective contraception (birth control) should be used during your treatment and for at least 4 weeks after the last SENCRESUS dose. Consult your doctor or healthcare professional for information regarding the Pregnancy Prevention Programme.
- Are pregnant, as SENCRESUS can cause major congenital malformations and fetal growth restriction
- Experience a rise in body temperature and decreased sweating.
- Experience behavioural changes and depression
- Develop unexplained lethargy or changes in mental status, your doctor may need to monitor your ammonia levels.

Taking other medicines with SENCRESUS:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please tell your doctor or pharmacist if you are taking any of the following medicines:

- Phenytoin, carbamazepine, valproic acid, phenobarbital, primidone, lamotrigine (medicines used for epilepsy (seizures) – they may affect the way SENCRESUS works)
- Digoxin (used to treat certain heart conditions, such as heart failure and some types of irregular heart beats)
- Oral contraceptives (SENCRESUS may affect the effectiveness of oral contraceptives and you must use an additional non-hormonal method of contraception, for instance a barrier method such as a condom)
- Hydrochlorothiazide (belongs to a group of medicines called diuretics (water tablets))
- Metformin (medicine used to treat diabetes by regulating the level of the sugar in the blood)
- Pioglitazone (anti-diabetic medicine which helps control the level of sugar in your blood)
- Sedatives and muscle relaxants medicines (may affect or decrease your thinking, concentration or muscle contraction and co-ordination)
- Alcohol (use together with SENCRESUS should be avoided as it could affect your concentration)
- Amitriptyline (medicine called tricyclic antidepressant to relieve the symptoms of depression)
- Dihydroergotamine (medicine for treatment of migraines)
- Haloperidol (medicines called 'neuroleptics' – they are used for illnesses affecting the way you think, feel or behave; for treatment of psychiatric conditions)

- Risperidone (belongs to a group of medicines called 'anti-psychotics' – they are used to treat conditions such as schizophrenia, where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious, or confused as well as other psychiatric conditions)
- Propranolol (belongs to a group of medicines called beta-blockers, which is used to treat high blood pressure and certain heart conditions)
- Sumatriptan (for migraine treatment)
- Pizotifen (belongs to a group of medicines called antihistamines or antiserotonin medicines and may be used to prevent headaches including migraine or cluster headaches)
- St John's Wort (*Hypericum perforatum*) (herbal remedy for treating mild depression)
- Lithium (belongs to a group of medicines called mood stabilisers. It works by stabilising the levels of chemicals in your brain that affect your mood)
- Glibenclamide (used for the treatment of diabetics who do not need insulin but who need more than just a diet to control their diabetes)
- Warfarin used to thin blood

SENCRESUS with food and drink

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

Pregnancy and breast feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

You should not become pregnant while taking SENCRESUS and should also not breast-feed your baby.

SENCRESUS can harm an unborn child. If you are of child-bearing age, talk to your doctor about other possible treatments and the conditions of the Pregnancy Prevention Programme. If the decision is made to use SENCRESUS you must use highly effective contraception during your treatment and for at least 4 weeks after the last SENCRESUS dose.

Pregnancy testing should be performed before initiating treatment with SENCRESUS.

Topiramate 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.

The active substance in SENCRESUS (topiramate) passes into human milk. You will need to discuss with your doctor whether to abstain from breastfeeding or withdraw treatment with SENCRESUS.

Driving and using machines

It is not always possible to predict to what extent SENCRESUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SENCRESUS affects them.

Do not drive or operate machinery if you are unsure of the effect that SENCRESUS will have on your abilities. It may affect your co-ordination or concentration.

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

3. HOW TO TAKE SENCRESUS:

Do not share medicines prescribed for you with any other person.

Always take SENCRESUS exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Your doctor will usually start you on a low dose of SENCRESUS and slowly increase your dose until the best dose is found for you. SENCRESUS tablets are to be swallowed whole. Avoid chewing the tablets as they may leave a bitter taste.

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

Your doctor will tell you how long your treatment with SENCRESUS will last. If you have the impression that the effect of SENCRESUS is too strong or too weak, tell your doctor or pharmacist.

If you take more SENCRESUS than you should:

If you take more SENCRESUS than you should, you may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heartbeats or fits.

In the event of an overdose consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Take the medicine pack with you.

If you forget to take SENCRESUS:

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 SENCRESUS:

Do not stop taking SENCRESUS unless told to do so by your doctor.

Your symptoms may return. If your doctor decides to stop SENCRESUS, your dose may be decreased gradually over a few days.

4. Possible side effects

SENCRESUS can cause side-effects.

Not all side-effects reported for SENCRESUS are included in this leaflet. Should your general health worsen while taking SENCRESUS, please consult your doctor, pharmacist or other health care professional for advice.

Get emergency medical help if you have any of these signs of an allergic reaction:

- tightness in the chest
- shortness of breath; difficulty in breathing; wheezing
- convulsions (seizures)
- fast or irregular heartbeats
- loss of consciousness; fainting

Call your doctor at once if you have any of these side-effects:

- thoughts of committing suicide or attempts to commit suicide
- severe skin reaction, including Stevens-Johnson syndrome, a life threatening skin condition in which the upper layer of the skin separates from the lower, and erythema multiforme, a condition of raised red spots that can blister

- changes in mood or behaviour, including anger, nervousness, sadness
- dizziness

These are all very serious side effects. If you have them, you may have had a serious reaction to SENCRESUS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- viral infections (flu-like illness)
- reduced number of red blood cells
- purple patches like bruising
- allergic reactions
- decrease or loss of appetite
- weight loss
- changes in thinking and alertness, including confusion, problems with concentration, memory or slowness in thinking
- disturbances with sexual function (loss of libido or erectile dysfunction)
- slurred speech
- involuntary shaking in the arms, hands or legs
- sensations like numbness, tingling, pins and needles
- difficulty with memory
- tiredness, drowsiness
- loss of strength
- disturbed or poor quality sleep
- visual disturbance, blurred vision, double vision

- involuntary eye movements
- Ear pain
- A spinning sensation and ringing in the ears
- stuffy, runny nose and sore throat
- Nosebleeds
- constipation; nausea; vomiting
- Increase saliva
- stomach pain; gastritis; drooling; distorted sense of taste
- hair loss
- skin rash and/or itchy skin
- Muscle pains, twitching and weakness
- Blood in the urine and painful urination
- Frequent urination
- Menstrual disturbances
- Thirst
- Increase in body temperature

Less frequent side effects

- abnormal blood counts, including reduced white blood cell count or platelet count
- Increased appetite
- Decreased blood potassium levels
- Decreased blood chloride levels
- Increased blood ammonia levels
- hallucinations
- restlessness or increased mental and physical activity

- panic disorders
- suicidal attempts and psychosis
- eye problems including dry eyes, light sensitivity
- high pressure in the eye
- blindness, blind spots and blurred vision
- eye pain
- sharpness of vision and loss of focusing ability
- Unusual dilation of pupil
- decrease of loss of hearing
- diarrhoea; dry mouth
- inflammation of the pancreas
- skin discolouration
- decrease or loss of sweating
- slow heartbeat
- palpitations
- low blood pressure
- severe narrowing of blood vessels in the cold
- difficulty breathing
- changes in the sound or tone of the voice
- hot flushing
- heartburn
- flatulence
- breath odor
- Burning and tingling of the mouth
- swelling of the joints
- musculoskeletal stiffness

- co-ordination issues
- deviation in walking pattern
- liver failure
- swelling of the face
- inflamed hair follicles
- itching
- numbness
- muscle fatigue and stiffness

Unknown side effects

- cough

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SENCRESUS.

5. How to store SENCRESUS

Store all medicines out of reach of children.

Store at or below 25 °C. Keep tablets in original blister pack until ready for use.

Protect from moisture.

Do not store in bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.

Do not keep outdated or medicines no longer needed. Be sure that any discarded medicine is out of reach of children.

6. Contents of the pack and other information

What SENCRESUS 25 contains:

The active substance is 25 mg topiramate.

Sugar free.

The other ingredients are Microcrystalline cellulose, povidone, colloidal silicon dioxide, sodium starch glycollate, magnesium stearate, Opadry white.

What SENCRESUS 50 contains:

The active substance is 50 mg topiramate.

Sugar free.

The other ingredients are: Microcrystalline cellulose, povidone, colloidal silicon dioxide, sodium starch glycollate, magnesium stearate, Opadry yellow.

What SENCRESUS 100 contains:

The active substance is 100 mg topiramate.

Sugar free.

The other ingredients are: Microcrystalline cellulose, povidone, colloidal silicon dioxide, sodium starch glycollate, magnesium stearate, Opadry yellow.

What SENCRESUS 200 contains:

The active substance is 200 mg topiramate.

Sugar free.

The other ingredients are Microcrystalline cellulose, povidone, colloidal silicon dioxide, sodium starch glycollate, magnesium stearate, Opadry maroon.

What SENCRESUS 25 looks like and contents of the pack

White, round, biconvex, film-coated tablets debossed with “G” on one side and “TO” over 25 on the other side.

Packed in cold forming aluminium blister pack, shiny on one side and dull (matte) on the other side, packed in an outer carton in pack sizes of 28 or 60 tablets.

What SENCRESUS 50 looks like and contents of the pack

Yellow, round, biconvex, film-coated tablets debossed with “G” on one side and “TO” over 50 on the other side.

Packed in cold forming aluminium blister pack, shiny on one side and dull (matte) on the other side, packed in an outer carton in pack sizes of 28 or 60 tablets.

What SENCRESUS 100 looks like and contents of the pack

Yellow, round, biconvex, film-coated tablets debossed with “G” on one side and “TO” over 100 on the other side.

Packed in cold forming aluminium blister pack, shiny on one side and dull (matte) on the other side, packed in an outer carton in pack sizes of 28 or 60 tablets.

What SENCRESUS 200 looks like and contents of the pack

Red, round, biconvex, film-coated tablets debossed with “G” on one side and “TO” over 200 on the other side.

Packed in cold forming aluminium blister pack, shiny on one side and dull (matte) on the other side, packed in an outer carton in pack sizes of 28 or 60 tablets.

Holder of Certificate of Registration

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