

PATIENT INFORMATION LEAFLET

KARAZEPIN 400 mg tablet

For oral use and this medicine should not chew.

- **Active substance:** 400 mg carbamazepine.
- **Excipients:** Microcrystalline cellulose, lactose (cows' milk), magnesium stearate, aerosol 200, Primojel (Sodium starch glycolate)

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, please ask to your doctor or pharmacist.*
- *This medicine is prescribed only for you. Do not pass it on to others.*
- *If you visit a doctor or hospital during usage of this medicine, please give information to your doctor that you are taking this medicine.*
- *Please strictly follow instructions in this prescribing leaflet. Do not take **lower or higher** dose than recommended dose.*

What is in this leaflet:

- 1. What KARAZEPIN is and what it is used for?**
- 2. What you need to know before you take KARAZEPIN.**
- 3. How to take KARAZEPIN?**
- 4. What are possible side effects?**
- 5. How to store KARAZEPIN?**

1. What KARAZEPIN is and what it is used for?

KARAZEPIN is presented in blister packs that contains 25 and 160 tablets.

KARAZEPIN is white, round and notched tablets. The tablet can cut in half.

Each tablet contains 400 mg carbamazepine that is active substance. Content of tablet is situated lactose that made of cows' milk.

KARAZEPIN belongs an drugs group that is called antiepileptic. This medicine can use for other diseases due to effect mechanism.

KARAZEPIN;

- In treatment of some epilepsy
- In treatment of trigeminal neuralgia diseases
- When the other medicine is not help you, it use to control serious mood disorders.

2. What you need to know before you take KARAZEPIN.

You can take KARAZEPIN only after physical examination.

In Han Chinese or Thai patients, the risk of serious skin reactions associated with carbamazepine or chemically similar compounds can be predicted by taking blood samples of these patients and testing them. Before taking KARAZEPIN, your doctor will recommend about whether a blood test is required.

DO NOT TAKE KARAZEPIN in the following situations:

- If you are allergic to carbamazepine or any of the ingredients of this medicine.
- If you have severe heart disease.
- If you have a problem with your bone marrow.
- If you have a defect in the production of porphyria, an important pigment in terms of liver function and blood production.
- If you or a member of your family has the rare blood pigment disorder called porphyria
- If you are allergic to similar drugs such as oxcarbazepine or phenytoin or a tricyclic antidepressant (e.g. amitriptyline)
- If you are already taking medicine to treat a mental illness called a monoamine oxidase inhibitor (MAOI), such as phenelzine (or have taken an MAOI in the last two weeks)

USE CAREFULLY KARAZEPIN in the following situations

Talk to your doctor or pharmacist before taking KARAZEPIN:

- If you have heart disease.
- If you have a history of liver or kidney disease.
- If you have kidney problems associated with low sodium blood level or if you have kidney problems and you are taking certain medicines that lower sodium blood levels (diuretics such as hydrochlorothiazide or furosemide).
- If you have glaucoma (increased pressure in the eye).
- If you have a difficulty to retain your urine.
- If you take oral contraceptive pill, KARAZEPIN can deactivate your oral contraceptive pill.
- If you have suffered from a mental illness in the past.
- If you are elderly.
- If you suffer from the sort of epilepsy where you get mixed seizures, which include absences.
- If you have blood disorders (including those caused by other drugs) or if you have ever suffered a reaction to any other medicine, which has affected your blood, for example a low white blood cell count (leucopenia).

- If you have had interrupted courses of treatment with carbamazepine.
- If you have irregular menstrual bleeding or if you have bleeding from the vagina.
- If an allergic reaction such as fever, rash or blisters develops along with swelling of the lymph nodes.
- If you experience severe skin reactions such as fever, rash, skin rash, blisters on the lips, eyes or mouth, peeling of the skin.
- If you experience an increase in the number of attack.
- If you have hepatitis,
- At any time, if you have thoughts of hurting yourself or killing yourself.
- If you have kidney problems associated with a low sodium blood level or if you have kidney problems and you are also taking certain medications that lower your sodium blood level

Please consult your doctor if any of the abovementioned warnings are apply to you, or have applied to you in the past.

Usage of KARAZEPIN with food and drink

You should not drink alcohol when you are taking KARAZEPIN.

You should not drink grapefruit juice or eat grapefruit because these can increase KARAZEPIN's effect. Effect of other fruit juices is not like this.

Pregnancy

Ask a doctor or pharmacist before taking the medicine.

If you are pregnant or plan to become pregnant, please talk to your doctor.

Alternative treatment methods should be recommended during treatment with KARAZEPIN.

It is important to control the seizures of epilepsy during pregnancy. However, if you use epilepsy medications during pregnancy, there is a potential risk to your baby. Your doctor will share you risk of KARAZEPIN in the duration of pregnant. You should not stop taking KARAZEPIN without consulting your doctor.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast Feeding

Ask a doctor or pharmacist before taking the medicine.

Tell your doctor if you are breastfeeding. The active substance in KARAZEPIN passes into breast milk. If your doctor considers it appropriate for you and your baby is closely monitored for side effects, you can continue breastfeeding while using the medicine. But if side effects develop, for example if your baby becomes more sleepy, stop breastfeeding and tell your doctor.

Usage of machine or vehicle

KARAZEPIN can cause you to feel sleepy, dizziness, blurred vision, double vision or muscle coordination problems, especially when starting treatment or when the dose is increased. Therefore, use caution when operating a vehicle or machine, or performing other activities that require attention.

Important information about some of the inactive ingredients of KARAZEPIN

KARAZEPIN contains lactose (cows' milk). If you have previously been told by your doctor that you have intolerance to certain sugars, you should consult your doctor before taking this medicinal product.

Usage with the other medicines

KARAZEPIN may interact with many other medicines, so remember to tell your doctor about the medications you are currently or recently taking.

It may be necessary to change the drug dose or sometimes discontinue one of the drugs.

Tell your doctor if you are taking the following medications:

- Hormonal contraceptives (birth control methods). KARAZEPIN affects the way contraceptives act on your body and you may experience sudden bleeding and spotting. It may also make contraceptive less effective and may have a risk of pregnancy. Your doctor can advise you on this and you should consider using other contraceptives.
- Hormone Replacement Treatment (HRT). KARAZEPIN may cause less effective of HRT.
- If you take any medicine for depression and anxiety.
- Corticosteroids. You may be taking these medications for inflammatory diseases such as asthma, inflammatory bowel disease, muscle and joint pain.
- Anticoagulants that prevent your blood from clotting.
- Antibiotics for the treatment of infections including skin infections and tuberculosis.
- Antifungal drugs used in the treatment of fungal infections.
- Painkillers containing paracetamol, dextropropoxyfene, tramadol, methadone or buprenorphine
- Other drugs for used treatment epilepsy

- Drugs used for high blood pressure and heart problems.
- Antihistamines (hay fever, itching etc. drugs used for allergies such as)
- Diuretics
- Cimetidine or omeprazole (drugs for used treatment gastric ulcers).
- Isotretinoin (a drug used to treat acne).
- Metoclopramide or aprepitant (anti-nausea drugs).
- Acetazolamide (a drug used in the treatment of increased eye pressure).
- Danazol or gestrinone (endometriosis treatments).
- Theophylline or aminophylline (used in the treatment of asthma).
- Cyclosporine, tacrolimus or sirolimus (immunosuppressants used after organ transplantation but sometimes used in the treatment of arthritis or psoriasis),
- Drugs used in the treatment of schizophrenia (e.g. paliperidone, aripiprazole).
- Cancer drugs (eg, temsirolimus, cyclophosphamide, lapatinib).
- Malaria medicine mefloquin
- Drugs used in HIV treatment.
- Levothyroxine (used in the treatment of hypothyroidism)
- Muscle relaxants,
- Tadalafil (used to treat impotence).
- Albendazole (used in the treatment of intestinal parasites).
- Bupropion (used to stop smoking).
- St. John's Wort [*Hypericum*] is a herbal medicine called St. John's Wort.
- Drugs or supplements containing vitamin B (nicotinamide).

Please inform your doctor or pharmacist if you are using or have recently used any medicine with or without a prescription.

3. How to take KARAZEPIN?

Instructions for proper use and dose / application frequency:

Your doctor will tell you need to take how much KARAZEPIN.

You should follow your doctor's recommend carefully. You should not exceed recommended dose.

You should be careful to take this medicine regularly and strictly as directed by your doctor.

Doing this so will help you get the best results and reduce the risk of side effects.

Do not take any over prescribed doses of KARAZEPIN, do not use the medication more often or longer than your doctor has prescribed.

You should not suddenly discontinue KARAZEPIN without consulting your doctor. Your doctor will tell you when and how you can stop taking this medicine.

Daily dose for epilepsy treatment:

Adults; complete tablet forms and oral suspensions (syrup) are generally initiated at doses from 100 mg to 200 mg once or twice a day. The dosage is then divided into 2 or 3 doses and gradually increased to 800 to 1200 mg per day (1600 mg or 2000 mg per day may be necessary in some patients). For elderly patients, a lower initial dose is recommended.

Children;

For 10-20 mg/kg body weight,

Between 5-10 years: 400-600 mg/day (2-3 times a day x 200 mg tablet)

Between 10-15 years: 600-1000 mg/day (3-5 times a day x 200 mg tablet)

Taking KARAZEPIN is not recommended in under the 5 years old children.

Daily dose for trigeminal neuralgia treatment:

The initial dose of 200 to 400 mg per day is slowly increased until no pain is left (generally 3-4 times a day 200 mg). Daily maximum dose is 1200 mg. For elderly patients, two times a day is recommended that is to say less than initial dose.

Daily dose in during periods of outburst (manic episode) of Bipolar mood disorders and maintenance therapy:

Daily dose is 400-600 mg (dose range is about 400-1600 mg).

Your doctor will tell you need to take how much dose.

Application form and method:

KARAZEPIN is taken 2-4 times a day depending on your medical condition that is to say dividing the daily dose. The dose prescribed by your doctor may differ from the dose listed above. In this case, follow your doctor's instructions.

You can take KARAZEPIN with or after a meal. Swallow tablets with a glass of water. If necessary, the tablets may be broken in half and broken into half.

Different age groups:

Usage for children:

KARAZEPIN can be used safely in children by following the instructions of your doctor. In children,

treatment is usually started at doses of 100-200 mg per day (daily 10-20 mg/kg body weight) and 400-600 mg per day.

Adolescents can use a dose of 600 to 1000 mg per day.

Usage for elderly:

KARAZEPIN can be used safely in the elderly by following your doctor's instructions.

Special use cases:

There is no information on dose adjustment in patients with kidney/liver failure.

Unless your doctor recommends otherwise follow these instructions.

Your doctor will advise you how long your treatment with KARAZEPIN.

Do not stop treatment early, because stopping KARAZEPIN treatment may make your disease worse.

If you have impression for effect of the KARAZEPIN for being too strong or weak, consult to your doctor or pharmacist.

If you use more KARAZEPIN than you need:

If you have an impression that you took KARAZEPIN more than you need, talk to your doctor or pharmacist.

If breathing difficulty, rapid and irregular heartbeat, unconsciousness, fainting, dizziness, nausea and / or vomiting develop, this dose may indicate a very high dose. Stop taking the medication and consult your doctor immediately.

If you forget to use KARAZEPIN:

Do not take double doses to compensate for forgotten doses.

Other things to know when taking KARAZEPIN:

It is very important that your doctor checks the progress of your condition through regular examinations.

Your doctor may order a blood test periodically, especially when you start taking KARAZEPIN. This is completely normal and does not require you to worry.

Before using any type of surgical treatment, including dental or emergency treatment, tell the competent doctor that you are using KARAZEPIN.

Possible effects of termination of treatment with KARAZEPIN

Stopping KARAZEPIN treatment may make your disease worse. Do not stop treatment unless directed to do so by your doctor.

4. What are possible side effects?

Like all medicines, KARAZEPIN can have side effects on persons who are sensitive to the materials in its content. The majority of possible side effects are mild to moderate and usually disappear after several days of treatment.

Side effects are classified as following categories:

Very common : minimum 1 in 10 patients are affected

Common : fewer than 1 in 10, but more than 1 in 100 patients are affected

Uncommon : fewer than 1 in 100, but more than 1 in 1000 patients are affected

Rare : fewer than 1 in 1000 patients are affected

Very rare : fewer than 1 in 10,000 patients are affected

Not known : frequency cannot be estimated from the available data

If you get any of the following side effects after taking KARAZEPIN, stop taking them and seek urgent medical advice IMMEDIATELY:

- Serious skin reactions such as skin rash, skin rash, swelling of the lips, eyes or mouth, and peeling accompanied by fever. These reactions may be more frequent in patients of Chinese or Thai origin.
- Oral ulcers or unexplained bruising or bleeding.
- Sore throat or high fever, or both
- Yellowing of your skin or eyes
- Swelling of ankles, feet or lower legs
- Symptom of any nerve disease or confusion
- Pain in joints and muscles, skin rash on the nasal bone and cheeks, or respiratory problems (lupus erythematosus)
- Fever, skin rash, arthralgias and blood and anomaly in kidney function test (these may be signs of multi-organ susceptibility disorder)
- Wheezing and cough, bronchospasm, difficulty breathing, fainting, rash, itching or swelling of the face (these may be symptoms of a severe allergic reaction).
- Pain in the area near the stomach

These are all very serious side effects.

You may need urgent medical attention or hospitalization.

Very Common:

- Reduction in the number of cells fighting infection; increases the risk of infection (leukopenia)
- Dizziness and fatigue
- Feeling of instability or difficulty in controlling movements
- Nausea or vomiting
- Changes in liver enzymes levels (usually asymptomatic)
- Severe skin reactions

Common:

- Easier bruising and bleeding tendency
- Fluid retention and swelling
- Weight gain
- Low sodium level in the blood will cause wooziness
- Headache
- Diplopia or blurred vision
- Desert mouth

Uncommon:

- Abnormal involuntary movements such as chills or other tics
- Abnormal eye movements
- Diarehea
- Bowel obstruction

Rare:

- Disease of the lymph nodes
- Folic acid deficiency
- Skin rash, arthralgias, fever, problems in kidneys and other organs
- Hallucinations
- Depression
- Loss of appetite
- Uneasiness
- Aggression
- Have a quick temper
- Wooziness
- Speech disorders
- Hypokinesia and famication in hands and feet

- Muscle weakness
- Hypertension (it may cause dizziness, redness of the face, headache, fatigue and irritability).
- Hypotension (it may cause fainting, dizziness, dizziness, confusion and blurred vision).
- Pulse changes
- Stomachache
- Liver problems inclusive hepatitis
- Lupus symptoms

Very rare:

- Changes in blood composition inclusive anemia
- A kind of genetic disorder that causes abdominal pain and muscle cramps (porphyria)
- Meninx inflammation (meningitis)
- Breast swelling and milk discharge
- Abnormal thyroid functions tests
- Thinning or failure in bones (osteomalacia)
- Softening of bones leading to increased risk of fracture (osteoporosis)
- Increase in plasma cholesterol levels
- Taste disorders
- Redness and inflammation of the eye (conjunctivitis)
- Feeling of pressure / pain in the eyes (glaucoma)
- Cataract
- Hearing disorders
- Heart disorders and circulatory abnormalities inclusive deep vein thrombosis (Symptoms may include tenderness, pain, swelling, feeling of warmth, discoloration of the skin, and pronounced superficial veins).
- Lung or respiratory disorders
- Severe skin reaction inclusive Stevens-Johnson syndrome
- Pain in the mouth or tongue
- Liver failure
- Increased skin sensitivity to sunlight
- Changes in the skin color
- Acne
- Extreme perspiration
- Acomia
- Pubescence on the body or face
- Muscle pain or spasm
- Reduction in male reproductive ability, loss of sexual desire or impotence
- Kidney failure
- Blood in urine
- Increased or decreased desire to urinate or difficulty in urination

Unknown:

- Herpes

- Bone marrow deficiency
- Temporary memory loss
- Colitis
- Fever, rash and hepatitis
- Skin rash
- Dark skin macula (lichenoid keratosis)
- Onikomadez
- Fracture
- Decreased bone marrow

Osteopenia, osteoporosis, fractures and bone disorders observed in taking KARAZEPIN patients. Tell your doctor if you are on long-term epilepsy, have a history of osteoporosis or are taking steroids.

If you get any side effects not listed in this leaflet, please give information to your doctor or pharmacist.

Reporting side effects

Talk to your doctor, pharmacist or nurse if you have any side effects that are included or not in the leaflet. Also report any side effect you may encounter to the "Drug Side Effects Report" at www.titck.gov.tr or call 0 800 314 00 08 "Turkey Pharmacovigilance Center (TUFAM)" side effect notification line. By reporting side effects, you will contribute to learning more about the safety of the medicine you are using.

5. How to store KARAZEPIN?

Keep KARAZEPIN out of the reach and sight of children, in the its original package.

Keep this medicine at room temperature lower than 25°C.

Use as agreeable with expiration dates.

Do not use KARAZEPIN after the expiration date on the packaging.

If you notice any defects in the product and/or package, do not use KARAZEPIN.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

Registration Holder: Terra İlaç ve Kimya Sanayi ve Ticaret A.Ş.
İstanbul/Turkey

Manufacturer: Myfarma İlaç San. ve Tic. A.Ş.
Tuzla/İstanbul

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