

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}TEGRETOL[®], ^{Pr}TEGRETOL[®] CR, ^{Pr}TEGRETOL[®] Suspension

carbamazepine tablets, carbamazepine controlled-release tablets, carbamazepine suspension

Read this carefully before you start taking **TEGRETOL, TEGRETOL CR or TEGRETOL Suspension** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TEGRETOL, TEGRETOL CR or TEGRETOL Suspension**.

Serious Warnings and Precautions

- **Blood:** Serious side effects affecting blood cell counts have been reported in patients taking TEGRETOL, TEGRETOL CR and TEGRETOL Suspension. These side effects are very rare but have been fatal. Other side effects that may happen with taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension include: low white blood cell count, bone marrow depression and liver problems, including liver failure. Your healthcare professional will do blood tests and frequent exams while you are taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension to watch for signs of these serious side effects. If you experience any of the following symptoms, contact your healthcare professional immediately:
 - signs of infections (fever, sore throat, rash, ulcers in the mouth, swollen glands)
 - signs of liver problems (yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite)
 - weakness, fatigue
 - easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin
 - shortness of breath
 - pale skin, lips and nail beds
- **Skin:** Serious and sometimes fatal skin reactions known as Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), have been reported in patients taking TEGRETOL, TEGRETOL CR and TEGRETOL Suspension. Other serious skin reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Acute Generalized Exanthematous Pustulosis (AGEP) and Maculopapular Rash have also been reported. Although very rare, serious forms of DRESS and AGEP may also lead to death. Some cases of these skin reactions have been genetically linked. Your healthcare professional may recommend a blood test to see if you are at risk before you start taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension. If you experience any of the following symptoms, contact your healthcare professional immediately:
 - a rash or any serious skin reactions such as red skin, blistering of the lips, eyes or mouth, and skin peeling accompanied by fever
 - swollen glands
 - joint pain
 - enlargement of the liver and/or the spleen with symptoms such as flu-like feeling, yellowing of the skin or eyes
 - problems related to the lungs, kidneys, pancreas, heart, bone marrow, thymus, and colon with symptoms such as shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often
- **Cancer:** Taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension may increase your risk of developing certain cancers. Before taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension, discuss the potential benefits and possible risks of this treatment with your healthcare professional.

What are TEGRETOL, TEGRETOL CR and TEGRETOL Suspension used for?

TEGRETOL, TEGRETOL CR and TEGRETOL Suspension are used to treat:

- **Epilepsy:** TEGRETOL, TEGRETOL CR and TEGRETOL Suspension can be used alone or with other anticonvulsant drugs to reduce the number of seizures in adults and children 6 years of age or older.
- **Trigeminal Neuralgia:** TEGRETOL, TEGRETOL CR and TEGRETOL Suspension relieve the pain of trigeminal neuralgia in adults. TEGRETOL, TEGRETOL CR and TEGRETOL Suspension should not be used to relieve trivial pain in the face or headaches.
- **Mania and Bipolar Disorders:** TEGRETOL, TEGRETOL CR and TEGRETOL Suspension can be used alone or together with the medicine lithium to treat acute mania or bipolar disorder in adults. TEGRETOL, TEGRETOL CR and TEGRETOL Suspension can be used if you are unable to take other antimanic drugs or do not respond to them.

How do TEGRETOL, TEGRETOL CR and TEGRETOL Suspension work?

TEGRETOL, TEGRETOL CR and TEGRETOL Suspension belong to the family of medicines called anticonvulsants for treating epilepsy. TEGRETOL, TEGRETOL CR and TEGRETOL Suspension are also used for treating the pain of trigeminal neuralgia and for treating mania.

What are the ingredients in TEGRETOL, TEGRETOL CR and TEGRETOL Suspension?

Medicinal ingredient: carbamazepine

Non-medicinal ingredients:

- **TEGRETOL:** carmellose sodium, cellulose compounds, magnesium stearate, silicon dioxide.
- **TEGRETOL CR:** acrylic esters, castor oil derivative, carmellose sodium, cellulose compounds, iron oxides, magnesium stearate, silicon dioxide, talc, titanium dioxide.
- **TEGRETOL Suspension:** citric acid, citrus-vanilla flavour, FD&C Yellow No. 6, pluronic polyol, potassium sorbate, propylene glycol, sucrose, sorbitol, water, xanthan gum.

TEGRETOL, TEGRETOL CR and TEGRETOL Suspension come in the following dosage forms:

- **TEGRETOL:** tablets; 200 mg
- **TEGRETOL CR:** controlled-release tablets; 200 mg, 400 mg
- **TEGRETOL Suspension:** oral suspension; each 5 mL (1 measure) contains 100 mg carbamazepine

Do not use TEGRETOL, TEGRETOL CR or TEGRETOL Suspension if you:

- are allergic (hypersensitive) to carbamazepine, tricyclic drugs (such as amitriptyline, trimipramine, imipramine), or to any of the other ingredients of TEGRETOL, TEGRETOL CR or TEGRETOL Suspension (See **What the non-medicinal ingredients are**)

- have severe heart disease (heart block).
- have liver disease.
- have a history of bone marrow depression.
- have had serious blood illnesses in the past.
- have a disturbance in the production of porphyrin, a pigment important for liver function and blood formation (also called hepatic porphyria).
- are also taking, or have recently taken, medicines belonging to a special group of antidepressants called monoamine-oxidase inhibitors (MAOIs). You should not take TEGRETOL, TEGRETOL CR or TEGRETOL Suspension within 14 days of taking a MAOI.
- are also taking itraconazole or voriconazole, medicines used to treat fungal infections.
- have a rare hereditary problem of fructose intolerance as TEGRETOL Suspension contains sorbitol.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TEGRETOL, TEGRETOL CR or TEGRETOL Suspension. Talk about any health conditions or problems you may have, including if you:

- have or have had any liver, kidney, heart or thyroid problems.
- have kidney problems associated with low levels of sodium in the blood or if you have kidney problems and you are also taking certain medicines that lower sodium blood levels (diuretics or “water pills” such as hydrochlorothiazide, furosemide).
- have any blood disorders (including those caused by other medicines).
- are taking delavirdine, a medicine used to treat HIV-1 infection.
- have ever shown any unusual sensitivity (rash or other signs of allergy such as swelling of lips, eyelids, face, throat, mouth, or sudden breathing problems) to oxcarbazepine or other drugs used to treat your condition. It is important to note that if you are allergic to TEGRETOL, TEGRETOL CR or TEGRETOL Suspension (carbamazepine), there is an approximately 1 in 4 (25%) chance that you could also have an allergic reaction to oxcarbazepine.
- get irregular vaginal bleeding or spotting.
- have increased pressure in the eye (glaucoma).
- have difficulty passing urine (urinary retention).

Other warnings you should know about:

Mental Health Problems and Thoughts of Suicide: Tell your healthcare professional if you have any mental health problems, including psychosis, agitation or confusion (especially in the elderly) or if you have ever had thoughts of harming or killing yourself.

A small number of patients taking antiepileptic drugs, including TEGRETOL, TEGRETOL CR and TEGRETOL Suspension, have had suicidal thoughts or behaviours. This might be more likely to happen when you first start taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension or when your dose is changed. Get immediate medical help if you, or someone you are caring for, has thoughts of suicide or suicidal behaviours.

Increase in Seizures: If you are taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension for epilepsy and you experience an increase in the number of seizures you are having, contact your healthcare professional immediately.

Falls: TEGRETOL, TEGRETOL CR and TEGRETOL Suspension may cause lack of coordination, dizziness, drowsiness, low blood pressure, confusion and sedation which may lead to falls, fractures and other injuries. This risk can be increased if you have other diseases, medical conditions or take other medications. Talk to your healthcare professional if you have questions about this.

Bone Mineral Density: Talk to your healthcare professional if you have, or have a family history, of bone disease or if you have taken antiepileptics (such as phenobarbital, phenytoin, primidone, oxcarbazepine, lamotrigine, sodium valproate and/or carbamazepine) for a prolonged period of time. Long-term use of antiepileptics, including TEGRETOL, TEGRETOL CR and TEGRETOL Suspension, can lead to weakened or brittle bones.

Eye Problems: TEGRETOL, TEGRETOL CR and TEGRETOL Suspension can cause eye problems. Periodic eye exams are recommended while you are taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension.

Alcohol: You should not drink alcohol while taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension. Talk to your healthcare professional about your alcohol consumptions and if you have a history of alcohol dependence.

TEGRETOL Suspension contains sorbitol which may cause stomach upset and diarrhea.

Fertility, Birth Control, Pregnancy and Breastfeeding:

- **Female Patients:**

- Avoid becoming pregnant while taking TEGRETOL, TEGRETOL CR and TEGRETOL Suspension. They may harm your unborn baby. Babies born to mothers who took TEGRETOL, TEGRETOL CR or TEGRETOL Suspension during pregnancy are at risk of serious side effects.
- Tell your healthcare professional immediately if you become pregnant or think you might be pregnant.
- Use highly effective birth control if you can get pregnant while taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension and for 2 weeks after your last dose.
- If you are using oral hormonal birth control (such as “The Pill”) it might not work while you are taking TEGRETOL, TEGRETOL CR or TEGRETOL

Suspension. Taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension while on oral birth control might also cause irregular periods. You must use a different or an additional non-hormonal method of birth control while you are taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension. Talk to your healthcare professional about the birth control options that are right for you.

- TEGRETOL, TEGRETOL CR and TEGRETOL Suspension pass into breastmilk. You should not breastfeed while you are taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension as they can cause serious side effects in your baby.

- **Male Patients:**

- TEGRETOL, TEGRETOL CR and TEGRETOL Suspension may affect your fertility. It may also cause abnormal sperm production. This means it may be difficult for you to father a child. Talk to your healthcare professional if you have questions about this.

Driving and Using Machines: TEGRETOL, TEGRETOL CR and TEGRETOL Suspension can cause dizziness, drowsiness, sleepiness, blurred or double vision and can affect your muscular coordination and your alertness. Do not drive or use machines until you know how you respond to TEGRETOL, TEGRETOL CR or TEGRETOL Suspension.

Blood Tests: TEGRETOL, TEGRETOL CR and TEGRETOL Suspension can cause abnormal blood test results. Your healthcare professional will perform blood tests before you start taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension and regularly during your treatment, and will interpret the results.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

This is particularly important for TEGRETOL, TEGRETOL CR and TEGRETOL Suspension, since many other medicines interact with them. You may need a change in your dose or, sometimes, to stop one of these other medicines.

Serious Drug Interactions

- TEGRETOL, TEGRETOL CR and TEGRETOL Suspension must not be taken within 14 days of monoamine oxidase (MAO) inhibitors, a special group of antidepressant medicines.
- TEGRETOL, TEGRETOL CR and TEGRETOL Suspension must not be taken with itraconazole and voriconazole, medicines used to treat fungal infections.

The following may also interact with TEGRETOL, TEGRETOL CR and TEGRETOL Suspension:

- Medicines used to treat pain and reduce inflammation such as; buprenorphine, methadone, paracetamol (acetaminophen), phenazone (antipyrine), tramadol, dextropropoxyphene, ibuprofen
- Medicines used to treat bacterial infections such as; doxycycline, rifabutin, erythromycin, troleandomycin, josamycin, clarithromycin, telithromycin, ciprofloxacin
- Medicines used to prevent blood clots such as; warfarin, phenprocoumon, dicoumarol, acenocoumarol, rivaroxaban, dabigatran, apixaban, edoxaban, ticlopidine
- Antidepressants such as; bupropion, citalopram, mianserin, nefazodone, sertraline, trazodone, tricyclic antidepressants (e.g. imipramine, amitriptyline, nortriptyline, clomipramine), desipramine, fluoxetine, fluvoxamine, paroxetine, viloxazine
- Medicines used to prevent seizures such as; oxcarbazepine, clobazam, clonazepam, ethosuximide, methsuximide, primidone, valproic acid, felbamate, lamotrigine, eslicarbazepine, zonisamide, tiagabine, topiramate, phenytoin, stiripentol, vigabatrin, valpromide, phenobarbital, phenisuximide, progabide, levetiracetam, brivaracetam
- Medicines used to treat fungal infections such as; itraconazole, ketoconazole, fluconazole, voriconazole, caspofungin
- Medicines used to treat parasites such as; praziquantel, albendazole
- Medicines used to treat tuberculosis infection such as; isoniazid, rifampicin
- Medicines used to treat cancer such as; imatinib, irinotecan, gefitinib, cyclophosphamide, lapatinib, temsirolimus, cisplatin, doxorubicin
- Medicines used to treat mental health problems such as; clozapine, haloperidol, bromperidol, olanzapine, quetiapine, risperidone, ziprasidone, aripiprazole, paliperidone, loxapine, lithium, metoclopramide
- Medicines used to treat HIV infection and AIDS such as; indinavir, ritonavir, saquinavir, delavirdine
- Medicines used to treat anxiety such as; alprazolam, midazolam
- Medicines used to treat heart problems such as; felodipine, digoxin, disopyramide, quinidine, propranolol, simvastatin, atorvastatin, lovastatin, ivabradine, verapamil, diltiazem
- Medicines used to treat stomach problems such as; cimetidine, omeprazole
- Medicines used to treat inflammation called corticosteroids such as; prednisolone, dexamethasone
- Medicines used to suppress the immune system such as; cyclosporin, everolimus, tacrolimus, sirolimus
- Medicines used to treat breathing problems such as; theophylline, aminophylline
- Diuretics or “water pills” such as; hydrochlorothiazide, furosemide
- Muscle relaxants such as; oxybutynin, dantrolene, pancuronium
- Terfenadine, a medicine used to treat allergies
- Acetazolamide, a medicine used to treat glaucoma
- Aprepitant, a medicine used to prevent nausea and vomiting
- Danazol, a medicine used to treat endometriosis and other conditions

- Isotretinoin, a medicine used to treat skin conditions such as acne
- Levothyroxine, a medicines used to treat thyroid problems
- Tadalafil, a medicine used to treat erectile dysfunction
- Hormonal birth control including estrogens and progesterones
- St. John's wort, an herbal medicine used to treat depression
- Vitamin B-3 such as; nicotinamide, niacinamide
- Avoid alcohol consumption when taking TEGRETOL, TEGRETOL CR and TEGRETOL Suspension.
- Do not drink grapefruit juice or eat grapefruit since this can increase the effect of TEGRETOL, TEGRETOL CR and TEGRETOL Suspension. Other juices, like orange juice or apple juice, do not have this effect.

How to take TEGRETOL, TEGRETOL CR and TEGRETOL Suspension:

- Always take TEGRETOL, TEGRETOL CR and TEGRETOL Suspension exactly as your healthcare professional has told you to. Your healthcare professional will decide on the dose that is right for you. Never increase or decrease your dose without talking to your healthcare professional.
- Do not stop taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension without talking to your healthcare professional. Your healthcare professional will tell you if and when you can stop taking this medicine.
- TEGRETOL, TEGRETOL CR and TEGRETOL Suspension should be taken in 2-4 divided doses daily, with meals whenever possible.
- Shake TEGRETOL Suspension well before you take it or else you may not receive the correct dose.
- TEGRETOL CR tablets should be swallowed whole with a little liquid during or after a meal. Do not crush or chew TEGRETOL CR tablets.

Usual dose:

- **Epilepsy:**
Adults and Children Over 12 Years of Age:
 Initial dose: 100 to 200 mg once or twice a day.
 Usual dose: 800 to 1200 mg daily in divided doses.
Children 6-12 Years of Age
 Initial dose: 100 mg a day in 2 to 4 divided doses.
 The dose will be increased gradually by your healthcare professional until the right dose is found.
- **Trigeminal Neuralgia:**
Adults:
 Initial dose: 100 mg twice a day.

Usual dose: 200 to 800 mg daily in divided doses.
Maximum dose: 1200 mg a day in divided doses.

- **Mania and Bipolar Disorders:**

Adults:

Initial dose: 200 to 400 mg daily in divided doses.
Usual dose: 400 to 1200 mg daily in divided doses.
Maximum dose: 1600 mg a day in divided doses.

Overdose:

If you think you, or a person you are caring for, have taken too much TEGRETOL, TEGRETOL CR or TEGRETOL Suspension, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you miss a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and return to your regular dosing schedule. Do not take a double dose to make up for the forgotten dose.

What are possible side effects from using TEGRETOL, TEGRETOL CR and TEGRETOL Suspension?

These are not all the possible side effects you may have when taking TEGRETOL, TEGRETOL CR or TEGRETOL Suspension. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- purple or reddish-purple bumps that may be itchy
- trembling, uncontrolled body movements, muscle spasm, loss of muscle coordination, weakness
- agitation or hostility (especially in the elderly), depression with restlessness, nervousness or other mood or mental changes, changes in behaviour, confusion, headache, memory loss
- blurred vision, double vision, itching with redness and swelling of the eye (conjunctivitis), uncontrolled eye movements
- difficulty speaking or slurred speech, taste disturbances, dry mouth, red and sore tongue, mouth sores
- ringing or other unexplained sounds in the ears, decreased hearing
- numbness, tingling in hands and feet

- unusual secretion of breast milk, breast enlargement in men, sexual disturbances (erectile dysfunction), male infertility
- increased sensitivity of the skin to sun, changes in skin colouring, acne, increased sweating
- reactivation of herpes virus infection (can be serious when the immune system is depressed)
- complete loss of the nails, loss of hair, excessive body and facial hair
- vomiting, nausea, loss of appetite, constipation, diarrhea, abdominal pain
- dizziness, sleepiness, unsteadiness, drowsiness, fatigue
- weight gain
- aching joints or muscles
- experience a fall due to dizziness, drowsiness, decrease in blood pressure, confusion

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Decreased White Blood Cells: fever, sore throat, rash, ulcers in the mouth, swollen glands, or more easily getting infections.	✓		
Suicidal Thoughts or Actions: thoughts, plans and actions taken for the purpose of killing or harming yourself.		✓	
COMMON			
Edema: swelling of the ankles, feet or lower legs.	✓		
RARE			
Systemic Lupus Erythematosus: red blotchy rash mainly on the face which may be accompanied by fatigue, fever, nausea, loss of appetite.	✓		
Hallucination: see or hear things that are not there.	✓		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
High Blood Pressure or Low Blood Pressure: dizziness, fainting, light-headedness.	√		
VERY RARE			
Glaucoma: pressure/pain in the eye.			√
Thrombophlebitis: swelling and redness along a vein which is extremely tender or painful when touched.		√	
Angioedema and Severe Allergic Reactions: swelling of the face, eyes, or tongue, difficulty swallowing, wheezing, hives and generalized itching, rash, fever, abdominal cramps, chest discomfort or tightness, difficulty breathing, unconsciousness.			√
Serious Skin Reactions: any combination of itchy skin rash, redness, blistering of the lips, eyes or mouth, skin peeling, accompanied by fever, chills, headache, cough, body aches or swollen lymph nodes, joint pain, enlargement of the liver and/or the spleen. Any problems related to the lungs, kidneys, pancreas, heart, bone marrow, thymus, and colon.			√
Liver Problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		√	
Meningitis: fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
bright light.			
Pancreatitis (inflammation of the pancreas): severe upper abdominal pain, vomiting, loss of appetite.	√		
Kidney Problems: severely decreased urine output, blood in the urine, frequent urination.	√		
Porphyrria: darkening of urine, severe abdominal pain, excessive sweating, vomiting, anxiety.		√	
Bone marrow depression (lack of all blood cells): tiredness, headache, being short of breath when exercising, dizziness, looking pale, frequent infections leading to fever, chills, sore throat or mouth ulcers, bleeding or bruising more easily than normal, nose bleeds.	√		
Neuroleptic Malignant Syndrome: muscular stiffness, high fever, altered consciousness, high blood pressure, excessive salivation.			√
Heart Problems: irregular heartbeat, chest pain, fast or unusually slow heartbeat, trouble breathing.	√		
Thromboembolism (blood clot): swelling, pain and redness in an arm or a leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations.			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Circulatory Collapse: the body is unable to circulate blood to the organs. This is very serious and can lead to death.			√
Disturbed consciousness, fainting.		√	
Hyponatremia (low sodium in the blood): lethargy, confusion, muscular twitching or significant worsening of convulsions.	√		
UNKNOWN FREQUENCY			
Inflammation of the colon: diarrhea, abdominal pain, fever.		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- **TEGRETOL:** Store at 15-25°C, protect from humidity.
- **TEGRETOL CR:** Store below 25°C, protect from humidity.

- **TEGRETOL Suspension:** Store below 30°C, protect from humidity and light.
- Keep TEGRETOL, TEGRETOL CR and TEGRETOL Suspension out of reach and sight of children.

If you want more information about TEGRETOL, TEGRETOL CR and TEGRETOL Suspension:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

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