IMPORTANT WARNING:

A small number of children, teenagers, and young adults (up to 24 years of age) who took antidepressants ('mood elevators') such as trazodone during clinical studies became suicidal (thinking about harming or killing oneself or planning or trying to do so). Children, teenagers, and young adults who take antidepressants to treat depression or other mental illnesses may be more likely to become suicidal than children, teenagers, and young adults who do not take antidepressants to treat these conditions. However, experts are not sure about how great this risk is and how much it should be considered in deciding whether a child or teenager should take an antidepressant. Children younger than 18 years of age should not normally take trazodone, but in some cases, a doctor may decide that trazodone is the best medication to treat a child's condition.

You should know that your mental health may change in unexpected ways when you take trazodone or other antidepressants even if you are an adult over age 24. You may become suicidal, especially at the beginning of your treatment and any time that your dose is increased or decreased. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: new or worsening depression; thinking about harming or killing yourself; or planning or trying to do so; extreme worry; agitation; panic attacks; difficulty falling asleep or staying asleep; aggressive behavior; irritability; acting without thinking; severe restlessness; and frenzied abnormal excitement. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor when you are unable to seek treatment on your own.

Your healthcare provider will want to see you often while you are taking trazodone, especially at the beginning of your treatment. Be sure to keep all appointments for office visits with your doctor.

The doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with trazodone. Read the information carefully and ask your doctor or pharmacist if you have any questions. You also can obtain the Medication Guide from the
FDA website: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/UCM096273

No matter your age, before you take an antidepressant, you, your parent, or your caregiver should talk to your doctor about the risks and benefits of treating your condition with an antidepressant or with other treatments. You should also talk about the risks and benefits of not treating your condition. You should know that having depression or another mental illness greatly increases the risk that you will become suicidal. This risk is higher if you or anyone in your family has or has ever had bipolar disorder (mood that changes from depressed to abnormally excited) or mania (frenzied, abnormally excited mood) or has thought about or attempted suicide. Talk to your doctor about your condition, symptoms, and personal and family medical history. You and your doctor will decide what type of treatment is right for you.

Why is this medication prescribed?

Trazodone is used to treat depression. Trazodone is in a class of medications called serotonin modulators. It works by increasing the amount of serotonin, a natural substance in the brain that helps maintain mental balance.

How should this medicine be used?

Trazodone comes as a tablet and as an extended-release (long-lasting) tablet to take by mouth. The tablet is usually taken with a meal or light snack two or more times a day. The extended-release tablet is usually taken once a day at bedtime on an empty stomach, either one hour before or two hours after a meal. To help you remember to take trazodone, take it around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take trazodone exactly as directed. Do not take more or less of it, take it more often, or take it for a longer time than prescribed by your doctor.

Swallow the extended-release tablets whole or broken in half on the score mark; do not chew or crush them.

Your doctor may start you on a low dose of trazodone and gradually increase your dose, not more than once every 3 to 4 days. Your doctor may decrease your dose once your condition is controlled.

Trazodone controls depression, but does not cure it. It may take 2 weeks or longer before you feel the full benefit of trazodone. Continue to take trazodone even if you feel well.

Do not stop taking trazodone without talking to your doctor. If you suddenly stop taking trazodone, you may experience withdrawal symptoms such as anxiety, agitation, or difficulty falling asleep or staying asleep. Your doctor will probably decrease your dose gradually.
Other uses for this medicine

Trazodone is also sometimes used to treat insomnia and schizophrenia (a mental illness that causes disturbed or unusual thinking, loss of interest in life, and strong or inappropriate emotions); anxiety (excessive worry). Trazodone is also sometimes used to control abnormal, uncontrollable movements that may be experienced as side effects of other medications. Talk to your doctor about the possible risks of using this medication for your condition.

This medication may be prescribed for other uses. Ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking trazodone,

- tell your doctor and pharmacist if you are allergic to trazodone or any other medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin); antidepressants; antifungals such as ketoconazole (Nizoral),itraconazole (Sporanox), or voriconazole (Vfend); aspirin and other NSAIDs such as ibuprofen (Advil, Motrin) and naproxen (Aleve, Naprosyn); certain medications for human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) such as atazanavir (Reyataz), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); cimetidine (Tagamet); cisapride (Propulsid); clarithromycin (Biaxin, in Prevpac); cyclosporine (Neoral, Sandimmune); danazol (Danocrine); delavirdine (Rescriptor); dexamethasone (Decadron); digoxin (Digitek, Lanoxin, Lanoxicaps); diltiazem (Cardizem, Dilacor, Tiazac); diuretics; disopyramide (Norpace); doxetilide (Tikosyn); erythromycin (E.E.S., E-Mycin, Erythrocin); isoniazid (INH, Nydrazid); medications for allergies, cough or colds; medications for anxiety, high blood pressure, irregular heartbeat, mental illness or pain; medication for seizures such as carbamazepine (Tegetrol), ethosuximide (Zarontin), phenobarbital (Luminal, Solfoton), and phenytoin (Dilantin); linezolid ( Zyvox); methylene blue; metronidazole (Flagyl); muscle relaxants; nefazodone; oral contraceptives (birth control pills); procarbazine (Procarbid, Pronesty); quinidine; rifabutin (Mycobutin); rifampin (Rifadin, Rimactane); sedatives; selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine (Prozac, Sarafem) and fluvoxamine (Luvox); sleeping pills; tranquilizers; sotalol (Betapace, Betapace AF); telithromycin (Ketek); thioridazine; troleandomycin (TAO); verapamil (Calan, Isoptin, Verelan); or zafirlukast (Accolate). Also, tell your doctor or pharmacist if you are taking the following medications, called MAO inhibitors, or if you have stopped taking them within the past 2 weeks: isocarboxazid (Marplan), phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), or tranylcypromine (Parnate). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have severe diarrhea or vomiting or think you may be dehydrated or if you have recently had a heart attack. Also tell your doctor if you have or have ever had high blood pressure, sickle cell anemia (a disease of the red blood cells), multiple myeloma (cancer of the plasma cells), leukemia (cancer of the white blood cells) cavernosal fibrosis, Peyronie's disease (a condition that affects the shape of the penis such as angulation), or heart, liver or kidney disease.
- Trazodone may cause QT prolongation (an irregular heart rhythm that can lead to fainting, loss of consciousness, seizures, or sudden death. Tell your doctor if you or anyone in your family has or has
ever had long QT syndrome (an inherited condition in which a person is more likely to have QT prolongation) or if you have or have ever had low levels of potassium or magnesium in your blood or an irregular heartbeat.

- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking trazodone, call your doctor.

- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking trazodone.

- you should know that trazodone may make you drowsy and affect your judgment. Do not drive a car or operate machinery until you know how this medication affects you.

- ask your doctor about the safe use of alcoholic beverages while you are taking trazodone. Alcohol can make the side effects from trazodone worse.

- you should know that trazodone may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.

- you should know that trazodone may cause angle-closure glaucoma (a condition where the fluid is suddenly blocked and unable to flow out of the eye causing a quick, severe increase in eye pressure which may lead to a loss of vision). Talk to your doctor about having an eye examination before you start taking this medication. If you have nausea, eye pain, changes in vision, such as seeing colored rings around lights, and swelling or redness in or around the eye, call your doctor or get emergency medical treatment right away.

**What special dietary instructions should I follow?**

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medicine.

**What should I do if I forget a dose?**

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

**What side effects can this medication cause?**

Trazodone may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- nausea
- vomiting
- bad taste in mouth
- diarrhea
- constipation
- changes in appetite or weight
- weakness or tiredness
- nervousness
- dizziness or lightheadedness
- feeling unsteady when walking
- decreased ability to concentrate or remember things
- confusion
- nightmares
- muscle pain
- dry mouth
- rash
- sweating
- changes in sexual desire or ability
- uncontrollable shaking of a part of the body
- numbness, burning, or tingling in the arms, legs, hands, or feet
- decreased coordination
- tired, red, or itchy eyes
- ringing in ears

Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS sections, call your doctor immediately or get emergency medical treatment:
- chest pain
- fast, pounding, or irregular heartbeat
- loss of consciousness (coma)
- fainting
- seizures
- shortness of breath
- unusual bruising or bleeding

Trazodone can cause painful, long lasting erections in males. In some cases emergency and/or surgical
treatment has been required and, in some of these cases, permanent damage has occurred. Talk to your doctor about the risk of taking trazodone.

Trazodone may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at http://www.fda.gov/Safety/MedWatch] or by phone [1-800-332-1088].

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from light, excess heat, and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include:

- vomiting
- drowsiness
- changes in heartbeat
- seizures
- difficulty breathing
- painful erection that does not go away

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are
admitted to a hospital. It is also important information to carry with you in case of emergencies.

**Brand names**

- Desyrel ® ¶
- Oleptro ®
- Trialodine ® ¶

¶ - This branded product is no longer on the market. Generic alternatives may be available.

Last Revised - 11/15/2014