



## Drugs and Supplements

# Tramadol (Oral Route)

## Description and Brand Names

### US Brand Name

ConZip	Descriptions
FusePaq Synapryn	
Rybix ODT	Tramadol is used to relieve moderate to moderately severe pain, including pain after surgery. The extended-release capsules or tablets are used for chronic ongoing pain.
Ryzolt	
Ultram	
Ultram ER	Tramadol belongs to the group of medicines called opioid analgesics. It acts in the central nervous system (CNS) to relieve pain.

When tramadol is used for a long time, it may become habit-forming, causing mental or physical dependence. However, people who have continuing pain should not let the fear of dependence keep them from using narcotics to relieve their pain. Mental dependence (addiction) is not likely to occur when narcotics are used for this purpose. Physical dependence may lead to withdrawal side effects if treatment is stopped suddenly. However, severe withdrawal side effects can usually be prevented by gradually reducing the dose over a period of time before treatment is stopped completely.

This medicine is available only under a restricted distribution program called the Opioid Analgesic REMS (Risk Evaluation and Mitigation Strategy) program.

This product is available in the following dosage forms:

- Capsule, Extended Release
- Suspension
- Tablet
- Tablet, Extended Release
- Capsule, Extended Release, 24 HR

## Before Using

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In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

## Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

## Pediatric

Appropriate studies have not been performed on the relationship of age to the effects of Rybix™ ODT and Ryzolt™ in children younger than 16 years of age. Safety and efficacy have not been established.

Conzip® extended-release capsules and Ultram® tablets should not be used in children younger than 12 years of age. It should not be used to relieve pain after surgery removal of tonsils or adenoids in any children. Severe breathing problems and deaths have been reported in some children who received tramadol after tonsil or adenoid surgery.

Appropriate studies have not been performed on the relationship of age to the effects of Ultram® ER extended-release tablets in the pediatric population. Safety and efficacy have not been established.

## Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of tramadol in the elderly. However, elderly patients are more likely to have unwanted side effects (eg, constipation, lightheadedness, dizziness, or fainting, stomach upset, weakness) and age-related liver, kidney, heart, or lung problems, which may require caution and an adjustment in the dose for patients receiving tramadol.

## Breastfeeding

Studies in women breastfeeding have demonstrated harmful infant effects. An alternative to this medication should be prescribed or you should stop breastfeeding while using this medicine.

## Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

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Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

- Furazolidone
- Iproniazid
- Isocarboxazid
- Linezolid
- Methylene Blue
- Moclobemide
- Nalmefene
- Naltrexone
- Nialamide
- Phenelzine
- Procarbazine
- Rasagiline
- Safinamide
- Selegiline
- Tranylcypromine

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Acepromazine
- Alfentanil
- Almotriptan
- Alprazolam
- Amifampridine
- Amineptine
- Amiodarone
- Amisulpride
- Amitriptyline
- Amitriptylinoxide
- Amobarbital
- Amoxapine
- Amphetamine
- Amprenavir
- Anileridine

- Aprepitant
- Aripiprazole
- Armodafinil
- Asenapine
- Atazanavir
- Baclofen
- Benperidol
- Benzhydrocodone
- Benzphetamine
- Boceprevir
- Bosentan
- Bromazepam
- Bromopride
- Bromperidol
- Brompheniramine
- Buprenorphine
- Bupropion
- Buspirone
- Butabarbital
- Butorphanol
- Cannabidiol
- Carbamazepine
- Carbinoxamine
- Carisoprodol
- Carphenazine
- Ceritinib
- Chloral Hydrate
- Chlordiazepoxide
- Chlorpheniramine
- Chlorpromazine
- Chlorzoxazone
- Cimetidine
- Cinacalcet
- Ciprofloxacin
- Citalopram

- Clarithromycin
- Clobazam
- Clomipramine
- Clonazepam
- Clopidogrel
- Clorazepate
- Clozapine
- Cobicistat
- Cocaine
- Codeine
- Conivaptan
- Crizotinib
- Cyclobenzaprine
- Cyclosporine
- Darunavir
- Delavirdine
- Desipramine
- Desmopressin
- Desvenlafaxine
- Dexamethasone
- Dexmedetomidine
- Dextroamphetamine
- Dextromethorphan
- Dezocine
- Diazepam
- Dibenzepin
- Dichloralphenazone
- Difenoxin
- Dihydrocodeine
- Diltiazem
- Diphenhydramine
- Diphenoxylate
- Dolasetron
- Donepezil
- Dothiepin

- Doxepin
- Doxylamine
- Dronedarone
- Droperidol
- Duloxetine
- Efavirenz
- Eletriptan
- Enflurane
- Enzalutamide
- Erythromycin
- Escitalopram
- Esketamine
- Eslicarbazepine Acetate
- Estazolam
- Eszopiclone
- Ethchlorvynol
- Ethopropazine
- Ethylmorphine
- Etravirine
- Fentanyl
- Flibanserin
- Fluconazole
- Fluoxetine
- Fluphenazine
- Flurazepam
- Fluspirilene
- Fluvoxamine
- Fosamprenavir
- Fosaprepitant
- Fosphenytoin
- Fospropofol
- Frovatriptan
- Granisetron
- Halazepam
- Haloperidol

- Halothane
- Hexobarbital
- Hydrocodone
- Hydromorphone
- Hydroxytryptophan
- Hydroxyzine
- Idelalisib
- Imatinib
- Imipramine
- Indinavir
- Isoflurane
- Itraconazole
- Ivacaftor
- Ketamine
- Ketazolam
- Ketobemidone
- Ketoconazole
- Levomilnacipran
- Levorphanol
- Lisdexamfetamine
- Lithium
- Lofepamine
- Lofexidine
- Lomitapide
- Lopinavir
- Lorazepam
- Lorcaserin
- Loxapine
- Lumacaftor
- Meclizine
- Melitracen
- Melperone
- Meperidine
- Mephobarbital
- Meproamate

- Meptazinol
- Mesoridazine
- Metaxalone
- Methadone
- Methamphetamine
- Methocarbamol
- Methohexital
- Methotrimeprazine
- Metoclopramide
- Mibefradil
- Midazolam
- Mifepristone
- Milnacipran
- Mirabegron
- Mirtazapine
- Mitotane
- Modafinil
- Molindone
- Moricizine
- Morphine
- Morphine Sulfate Liposome
- Nafcillin
- Nalbuphine
- Naratriptan
- Nefazodone
- Nelfinavir
- Nevirapine
- Nicomorphine
- Nilotinib
- Nitrazepam
- Nitrous Oxide
- Nortriptyline
- Olanzapine
- Ondansetron
- Opi Pramol



- Opium
- Opium Alkaloids
- Orphenadrine
- Oxazepam
- Oxcarbazepine
- Oxycodone
- Oxymorphone
- Palbociclib
- Palonosetron
- Papaveretum
- Paregoric
- Paroxetine
- Peginterferon Alfa-2b
- Pentazocine
- Pentobarbital
- Perampanel
- Periciazine
- Perphenazine
- Phenobarbital
- Phenytoin
- Pimozide
- Piperacetazine
- Pipotiazine
- Piritramide
- Posaconazole
- Prazepam
- Prednisone
- Primidone
- Prochlorperazine
- Promethazine
- Propofol
- Protriptyline
- Quazepam
- Quetiapine
- Quinidine

- Quinine
- Ramelteon
- Ranitidine
- Ranolazine
- Remifentanyl
- Remoxipride
- Rifabutin
- Rifampin
- Rifapentine
- Ritonavir
- Rizatriptan
- Rolapitant
- Saquinavir
- Scopolamine
- Secobarbital
- Sertindole
- Sertraline
- Sibutramine
- Sodium Oxybate
- St John's Wort
- Sufentanyl
- Sulpiride
- Sumatriptan
- Suvorexant
- Tapentadol
- Telaprevir
- Telithromycin
- Temazepam
- Terbinafine
- Thiethylperazine
- Thiopental
- Thiopropazate
- Thioridazine
- Tianeptine
- Tilidine

- Tizanidine
- Tolonium Chloride
- Topiramate
- Trazodone
- Triazolam
- Trifluoperazine
- Trifluperidol
- Triflupromazine
- Trimeprazine
- Trimipramine
- Tryptophan
- Venlafaxine
- Verapamil
- Vilazodone
- Voriconazole
- Vortioxetine
- Zaleplon
- Ziprasidone
- Zolmitriptan
- Zolpidem
- Zopiclone
- Zotepine

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Warfarin

## Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following is usually not recommended, but may be unavoidable in some cases. If used together, your doctor may change the dose or how often you use this medicine, or give you special instructions about the use of food, alcohol, or tobacco.

- Ethanol
- Grapefruit Juice

## Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Alcohol abuse, history of or
- Brain tumor or
- Depression, history of or
- Drug abuse or dependence, history of or
- Gallstones or
- Head injury or
- Hormonal problems or
- Increased pressure in the head or
- Infections of the central nervous system (CNS) or
- Lung or breathing problems (eg, COPD, cor pulmonale, hypercapnia, hypoxia) or
- Mental illness, history of or
- Phenylketone allergy, history of or
- Seizures or epilepsy, history of or
- Stomach problems, severe—Use with caution. May increase risk for more serious side effects.
- Kidney disease or
- Liver disease (including cirrhosis)—Use with caution. The effects may be increased because of slower removal of the medicine from the body.
- Lung or breathing problems (eg, asthma, hypercapnia, respiratory depression), severe or
- Stomach or bowel blockage (eg, paralytic ileus) or
- Surgery (eg, nasopharyngeal tonsils, tonsils)—Should not be used in patients with these conditions.
- Phenylketonuria (PKU)—The orally disintegrating tablet contains phenylalanine, which can make this condition worse.

## Proper Use

Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. If too much of this medicine is taken for a long time, it may become habit-forming (causing mental or physical dependence) or cause an overdose.

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It is very important that you understand the rules of the Opioid Analgesic REMS program to prevent addiction, abuse, and misuse of acetaminophen and codeine combination. This medicine should come with a Medication Guide. Read and follow the instructions carefully. Read it again each time you refill your prescription in case there is new information. Ask your doctor if you have any questions.

If you think that this medicine is not working as well after you have been taking it for a few weeks, do not increase the dose. Instead, check with your doctor.

If you are using the disintegrating tablet, make sure your hands are dry before you handle it. Do not open the blister pack that contains the tablet until you are ready to take it. Remove the tablet from the blister pack by peeling back the foil, then taking the tablet out. Do not push the tablet through the foil. Do not break, crush, or chew it. Place the tablet in your mouth. It should melt quickly. After the tablet has melted, swallow or take a sip of water.

Swallow the extended-release capsule, extended-release tablet, and tablet whole with liquids. Do not break, crush, chew, snort, or inject it.

## Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For chronic pain:
  - For oral dosage form (extended-release capsules):
    - Adults—At first, 100 milligrams (mg) once a day. Your doctor may increase your dose as needed. However, the dose is usually not more than 300 mg per day.
    - Children 12 years of age and older—Use and dose must be determined by your doctor.
    - Children younger than 12 years of age—Should not be used in these patients.
  - For oral dosage form (extended-release tablets):
    - Adults—At first, 100 milligrams (mg) once a day. Your doctor may increase your dose as needed. However, the dose is usually not more than 300 mg per day.
    - Children—Use and dose must be determined by your doctor.
- For moderate to severe pain:
  - For oral dosage form (disintegrating tablets):
    - Adults and children 16 years of age and older—At first, 50 to 100 milligrams (mg) every 4 to 6 hours as needed. Your doctor may increase your dose as needed. However, the dose is usually not more than 400 mg per day.
    - Children younger than 16 years of age—Use and dose must be determined by your doctor.

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- For oral dosage form (tablets):
  - Adults—At first, 25 milligrams (mg) per day, taken every morning. Your doctor may increase your dose as needed and tolerated. However, the dose is usually not more than 400 mg per day.
  - Children 12 years of age and older—Use and dose must be determined by your doctor.
  - Children younger than 12 years of age—Should not be used in these patients.

## Missed Dose

If you miss a dose of this medicine, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

## Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

## Precautions

It is very important that your doctor check your or your child's progress at regular visits, especially within the first 24 to 72 hours of treatment to make sure the medicine is working properly. Blood tests may be needed to check for unwanted effects.

Do not use this medicine if you are using or have used an MAO inhibitor (MAOI) such as isocarboxazid [Marplan®], linezolid [Zyvox®], phenelzine [Nardil®], selegiline [Eldepryl®], tranylcypromine [Parnate®]) within the past 14 days.

Check with your doctor before using this medicine with alcohol or other medicines that affect the central nervous system (CNS). The use of alcohol or other medicines that affect the CNS with tramadol may worsen the side effects of this medicine, such as dizziness, poor concentration, drowsiness, unusual dreams, and trouble with sleeping. Some examples of medicines that affect the CNS are antihistamines or medicine for allergies or colds, sedatives, tranquilizers, or sleeping medicines, medicine for depression, medicine for anxiety, prescription pain medicine or narcotics, medicine for attention deficit and hyperactivity disorder, medicine for seizures or barbiturates, muscle relaxants, or anesthetics, including some dental anesthetics.

Using this medicine while you are pregnant may cause neonatal withdrawal syndrome in your newborn baby. Check with your doctor right away if your baby has an abnormal sleep pattern, diarrhea, a high-pitched cry, irritability, shakiness or tremors, weight loss, vomiting, or fails to gain weight. Tell your doctor right away if you think you are pregnant or if you plan to become pregnant while using this medicine.

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Tramadol is highly metabolized in the body. Some people change tramadol to a stronger product (O-desmethyltramadol) more quickly than others. These individuals are called "ultra-rapid metabolizers of tramadol". Contact your doctor immediately if you experience extreme sleepiness, confusion, or shallow breathing. These symptoms may indicate that you are an "ultra-rapid metabolizer of tramadol." As a result, there is too much O-desmethyltramadol in the body and more side effects of O-desmethyltramadol than usual. Children may be especially sensitive to this effect (eg, serious breathing problems, death). Do not give this medicine to:

- Children younger than 12 years of age.
- Children younger than 18 years of age who have had surgery removal of tonsils or adenoids.
- Children 12 to 18 years of age who have a high risk for breathing problems (eg, obstructive sleep apnea, obesity, lung disease).

If a nursing mother is an ultra-rapid metabolizer of tramadol, it could lead to an overdose in the nursing baby and cause very serious side effects.

For nursing mothers using this medicine:

- Talk to your doctor if you have any questions about taking tramadol or about how this medicine may affect your baby.
- Call your doctor if you become extremely tired and have difficulty caring for your baby.
- Your baby should generally nurse every 2 to 3 hours and should not sleep more than 4 hours at a time.
- Check with your doctor, hospital emergency room, or local emergency services (eg, "call 9-1-1") immediately if your baby shows signs of increased sleepiness (more than usual), difficulty breastfeeding, difficulty breathing, or limpness. These may be symptoms of an overdose and need immediate medical attention.

Check with your doctor right away if you or your child have anxiety, restlessness, a fast heartbeat, fever, sweating, muscle spasms, twitching, nausea, vomiting, diarrhea, or see or hear things that are not there. These may be symptoms of a serious condition called serotonin syndrome. Your risk may be higher if you also take certain other medicines that affect serotonin levels in your body.

This medicine may cause some people to be agitated, irritable, or display other abnormal behaviors. It may also cause some people to have suicidal thoughts and tendencies or to become more depressed. Make sure your doctor knows if you have trouble sleeping, get upset easily, have a big increase in energy, or start to act reckless. Also tell your doctor if you have any sudden or strong feelings, such as feeling nervous, angry, restless, violent, or scared. Let your doctor know if you or anyone in your family has bipolar disorder (manic-depressive disorder) or has tried to commit suicide.

This medicine may cause serious allergic reactions, including anaphylaxis. This can be life-threatening and requires immediate medical attention. Call your doctor right away if you or your child have a rash, itching, hoarseness, trouble breathing, trouble swallowing, or any swelling of your hands, face, or mouth while you are using this medicine.

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This medicine may cause some people to become drowsy, dizzy, or lightheaded. Do not drive or do anything else that could be dangerous until you know how this medicine affects you.

Dizziness, lightheadedness, or fainting may occur, especially when you get up suddenly from a lying or sitting position. Getting up slowly may help. Also, lying down for a while may relieve dizziness or lightheadedness. If this problem continues or gets worse, check with your doctor right away.

Before having any kind of surgery (including dental surgery) or emergency treatment, tell the doctor or dentist in charge that you are taking this medicine. Serious side effects can occur if your doctor or dentist gives you certain medicines without knowing that you have been taking tramadol.

If you think you or someone else may have taken an overdose of tramadol, get emergency help at once. Signs of an overdose include: convulsions (seizures), difficult or troubled breathing, irregular, fast or slow, or shallow breathing, pale or blue lips, fingernails, or skin, pinpoint pupils of the eyes, or trouble breathing.

Do not change your dose or suddenly stop using this medicine without first checking with your doctor. Your doctor may want you to gradually reduce the amount you are using before stopping it completely. This may help prevent worsening of your condition and reduce the possibility of withdrawal symptoms, such as abdominal or stomach cramps, anxiety, fever, nausea, runny nose, sweating, tremors, or trouble with sleeping.

Using too much of this medicine may cause infertility (unable to have children). Talk with your doctor before using this medicine if you plan to have children.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

## Side Effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

### Less common

- Abnormal or decreased touch sensation
- blisters under the skin
- bloating
- blood in the urine
- blood pressure increased
- blurred vision
- change in walking and balance
- chest pain or discomfort



- chills
- dark urine
- difficult urination
- dizziness or lightheadedness when getting up from a lying or sitting position
- fainting
- fast heartbeat
- frequent urge to urinate
- gaseous abdominal or stomach pain
- indigestion
- irregular heartbeat
- loss of memory
- numbness and tingling of the face, fingers, or toes
- pain in the arms, legs, or lower back, especially pain in the calves or heels upon exertion
- pain or discomfort in the arms, jaw, back, or neck
- pains in the stomach, side, or abdomen, possibly radiating to the back
- pale, bluish-colored or cold hands or feet
- recurrent fever
- seeing, hearing, or feeling things that are not there
- seizures
- severe cramping
- severe nausea
- severe redness, swelling, and itching of the skin
- stomach fullness
- sweating
- swelling of the hands, ankles, feet, or lower legs
- trembling and shaking of the hands or feet
- trouble performing routine tasks
- weak or absent pulses in the legs
- yellow eyes or skin

**Incidence not known**

- Agitation
- confusion
- cough
- darkening of the skin

- diarrhea
- difficulty swallowing
- dizziness
- fever
- hives, itching, skin rash
- irregular heartbeat, recurrent
- loss of appetite
- mental depression
- nausea
- overactive reflexes
- poor coordination
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- restlessness
- shivering
- talking or acting with excitement you cannot control
- tightness in the chest
- twitching
- unusual tiredness or weakness
- vomiting

Get emergency help immediately if any of the following symptoms of overdose occur:

### **Symptoms of overdose**

- Change in consciousness
- decreased awareness or responsiveness
- difficulty with breathing
- lack of muscle tone
- lightheadedness
- loss of consciousness
- pinpointed pupils of the eyes
- severe sleepiness
- slow or irregular heartbeat
- unusual tiredness

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with

your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

**More common**

- Constipation
- discouragement
- drowsiness
- dry mouth
- feeling of warmth
- feeling sad or empty
- feeling unusually cold
- general feeling of discomfort or illness
- headache
- heartburn
- irritability
- itching or skin rash
- joint pain
- loss of interest or pleasure
- loss of strength or weakness
- muscle aches and pains
- redness of the face, neck, arms, and occasionally, upper chest
- runny nose
- sleepiness or unusual drowsiness
- sore throat
- stomach pain
- stuffy nose
- tiredness
- trouble concentrating
- unusual feeling of excitement
- weakness

**Less common**

- Abnormal dreams
- appetite decreased
- back pain
- bladder pain

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- blistering, crusting, irritation, itching, or reddening of the skin
- bloody or cloudy urine
- body aches or pain
- change in hearing
- clamminess
- cough producing mucus
- cracked, dry, or scaly skin
- decreased interest in sexual intercourse
- difficult, burning, or painful urination
- difficulty with moving
- disturbance in attention
- ear congestion
- ear drainage
- earache or pain in the ear
- excessive gas
- falls
- false or unusual sense of well-being
- feeling hot
- feeling jittery
- general feeling of bodily discomfort
- goosebumps
- headache, severe and throbbing
- hoarseness
- inability to have or keep an erection
- itching, pain, redness, swelling, tenderness, or warmth on the skin
- joint sprain, stiffness, or swelling
- loss in sexual ability, desire, drive, or performance
- loss of voice
- lower back or side pain
- muscle aching or cramping
- muscle injury
- muscle pain, stiffness, spasms, or twitching
- nasal congestion
- neck pain
- night sweats

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- pain in the limbs
- pain or tenderness around the eyes and cheekbones
- pain, swelling, or redness in the joints
- skin discoloration
- trouble in holding or releasing urine
- trouble with sleeping
- weight increased or decreased

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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