Tapentadol immediate-release oral tablets
MEDICATION GUIDE

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine talk to your doctor, pharmacist, or health care provider.

What is this medicine?
TAPENTadol (ta PEN ta dol) is a pain reliever. It is used to treat moderate to severe pain.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?
Take this medicine by mouth with a glass of water. If the medicine upsets your stomach, take it with food or milk. Follow the directions on the prescription label. Do not take more than you are told to take.

A special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time.

Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Overdosage: If you think you’ve taken too much of this medicine contact a poison control center or emergency room at once.

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NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?
If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What should I tell my health care provider before I take this medicine?
They need to know if you have any of these conditions:
• Gallbladder disease
• Head injury
• History of a drug or alcohol abuse problem
• If you often drink alcohol
• Kidney disease
• Liver disease
• Lung or breathing disease, like asthma
• Prostate disease
• Seizures
• Stomach or intestine problems
• Thyroid disease
• An unusual or allergic reaction to tapentadol, other medicines, foods, dyes, or preservatives
• Pregnant or trying to get pregnant
• Breast-feeding

What may interact with this medicine?
Do not take this medicine with any of the following medications:
• MAOIs like Carbex, Eldepryl, Marplan, Nardil, and Parnate

This medicine may also interact with the following medications:
• Alcohol
• Antihistamines for allergy, cough, and cold
• Atropine
• Buprenorphine
• Certain medicines for bladder problems like oxybutynin, tolterodine
• Certain medicines for depression, anxiety, or psychotic disturbances
• Certain medicines for migraine headache like almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan
• Certain medicines for Parkinson’s disease like benztropine, trihexyphenidyl
• Certain medicines for stomach problems like dicyclomine, hyoscyamine
• Certain medicines for travel sickness like scopolamine
Ipratropium
Medicines for seizures like carbamazepine, phenobarbital, phenytoin
Medicines for sleep
Muscle relaxants
Narcotic medicines (opiates) for pain
Phenothiazines like chlorpromazine, mesoridazine, prochlorperazine, thioridazine

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:
- Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- Anxious
- Breathing problems
- Changes in vision
- Confusion
- Fast, irregular heartbeat
- Feeling faint or lightheaded, falls
- Hallucinations
- Muscle spasms
- Seizures
- Trouble passing urine or change in the amount of urine
- Unusually weak or tired

Side effects that usually do not require medical attention (Report these to your doctor or health care professional if they continue or are bothersome.):
- Changes in emotions or moods
- Constipation
- Headache
- Nausea, vomiting
- Stomach upset

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?

Tell your doctor or health care professional if your pain does not go away, if it gets worse, or if you have new or a different type of pain. You may develop tolerance to the medicine. Tolerance means that you will need a higher dose of the medicine for pain relief. Tolerance is normal and is expected if you take the medicine for a long time.

Do not suddenly stop taking your medicine because you may develop a severe reaction. Your body becomes used to the medicine. This does NOT mean you are addicted. Addiction is a behavior related to getting and using a drug for a non-medical reason. If you have pain, you have a medical reason to take pain medicine. Your doctor will tell you how much medicine to take. If your doctor wants you to stop the medicine, the dose will be slowly lowered over time to avoid any side effects.

You may get drowsy or dizzy. Do not drive, use machinery, or do anything that needs mental alertness until you know how this medicine affects you. Do not stand or sit up quickly, especially if you are an older patient. This reduces the risk of dizzy or fainting spells. Alcohol may interfere with the effect of this medicine. Avoid alcoholic drinks.

There are different types of narcotic medicines (opiates) for pain. If you take more than one type at the same time, you may have more side effects. Give your health care provider a list of all medicines you use. Your doctor will tell you how much medicine to take. Do not take more medicine than directed. Call emergency for help if you have problems breathing.

This medicine will cause constipation. Try to have a bowel movement at least every 2 to 3 days. If you do not have a bowel movement for 3 days, call your doctor or health care professional.

Where should I keep my medicine?

Keep out of the reach of children. This medicine can be abused. Keep your medicine in a safe place to protect it from theft. Do not share this medicine with anyone. Selling or giving away this medicine is dangerous and against the law.

Store at room temperature between 15 and 30 degrees C (59 and 86 degrees F). Protect from moisture. Throw away any unused medicine after the expiration date.

Discard unused medicine and used packaging carefully. Pets and children can be harmed if they find used or lost packages. Follow the directions in the MedGuide.

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