

MEDICATION GUIDE
TRADENAME™
(tapentadol)
immediate release oral tablets

- **Keep TRADENAME™ in a safe place to prevent theft. Selling or giving away TRADENAME™ may harm others, and is against the law.**
- **Tell your doctor if you (or a family member) have ever abused or been dependent on alcohol, prescription medicines, or street drugs.**

Read the Medication Guide that comes with TRADENAME™ before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or your treatment. Talk to your doctor if you have any questions.

What is the most important information I should know about TRADENAME™?

TRADENAME™ is a tablet that contains tapentadol, a strong medicine that is a pain medicine.

Use TRADENAME™ exactly how your doctor tells you to. Do not use TRADENAME™ if it has not been prescribed for you.

You should not take TRADENAME™ if your pain is mild and can be controlled with other pain medicines such as non-steroidal anti-inflammatory medicines (NSAIDs) or acetaminophen.

What is TRADENAME™?

- TRADENAME™ is a prescription medicine that is used in adults 18 years of age or older to treat moderate to severe pain that is expected to last a short time.

TRADENAME™ is for short-term use only because the risks for withdrawal symptoms, abuse and addiction are higher when TRADENAME™ is used longer.

Who should not take TRADENAME™?

Do not take TRADENAME™ if you:

- have severe lung problems
- have a gastrointestinal problem called paralytic ileus in which the intestines are not working normally.

- take a monoamine oxidase inhibitor (MAOI) medicine or have taken an MAOI within the last 14 days. Ask your doctor or pharmacist if any of your medicines is an MAOI.

What should I tell my doctor before taking TRADENAME™?

TRADENAME™ may not be right for you. Tell your doctor about all your medical conditions, including if you have:

- trouble breathing or lung problems
- or had a head injury
- liver or kidney problems
- convulsions or seizures
- dependency problems with alcohol
- pancreas or gall bladder problems
- past or present substance abuse or drug addiction. There is a risk of abuse or addiction with narcotic pain medicines. If you have abused drugs in the past, you may have a higher chance of developing abuse or addiction again while using TRADENAME™.
- are pregnant or plan to become pregnant
- are breast-feeding. You should not breast-feed while taking TRADENAME™.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Using TRADENAME™ with other medicines can cause serious side effects. The doses of some other medicines may need to be changed. Your doctor can tell you what medicines can be safely taken with TRADENAME™. Especially tell your doctor if you take:

- **Monoamine Oxidase Inhibitors (MAOIs).** See "Who should not take TRADENAME™."
- **any medicine that makes you sleepy.** TRADENAME™ can make you sleepy and affect your breathing. Taking these medicines together can be dangerous.

How should I take TRADENAME™?

- Do not take TRADENAME™ unless it has been prescribed for you by your doctor.
- Take TRADENAME™ exactly as prescribed by your doctor.
- **Do not change the dose of TRADENAME™ unless your doctor tells you to.** Your doctor may change your dose after seeing how the medicine affects you. Do not use TRADENAME™ more often than prescribed. Call your doctor if your pain is not well controlled while taking TRADENAME™.
- Follow your doctor's instructions about how to slowly stop taking TRADENAME™ to help lessen withdrawal symptoms.
- TRADENAME™ can be taken with or without food.

What should I avoid while taking TRADENAME™?

- Do not drive, operate machinery, or participate in any other possibly dangerous activities until you know how you react to this medicine. TRADENAME™ can make you sleepy.
- You should not drink alcohol while using TRADENAME™. Alcohol increases your chance of having dangerous side effects.

What are the possible side effects of TRADENAME™?

TRADENAME™ can cause serious side effects including:

- **Life-threatening breathing problems. Call your doctor right away or get emergency medical help if you:**
 - have trouble breathing, or have slow or shallow breathing
 - have a slow heartbeat
 - have severe sleepiness
 - have cold, clammy skin
 - feel faint, dizzy, confused, or can not think, walk or talk normally
 - have a seizure
 - have hallucinations
- **Physical Dependence.** TRADENAME™ can cause physical dependence. Talk to your doctor about slowly stopping TRADENAME™ to avoid getting sick with withdrawal symptoms. You could become sick with uncomfortable symptoms because your body has become used to the medicine. Tell your doctor if you have any of these symptoms of withdrawal: feeling anxious, sweating, sleep problems, shivering, pain, nausea, tremors, diarrhea, upper respiratory symptoms, hallucinations, hair "standing on end." Physical dependence is not the same as drug addiction. Your doctor can tell you more about the differences between physical dependence and drug addiction.
- **Serotonin syndrome.** Serotonin syndrome is a rare, life-threatening problem that could happen if you take TRADENAME™ with Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs), Monoamine Oxidase Inhibitors (MAOIs), triptans or certain other medicines. Call your doctor or get medical help right away if you have any one or more of the these symptoms: you feel agitated, have hallucinations, coma, rapid heart beat, feel overheated, loss of coordination, over active reflexes, nausea, vomiting, or diarrhea.
- **Seizures.** TRADENAME™ can cause seizures in people who are at risk for seizures or who

have epilepsy. Tell your doctor right away if you have a seizure and stop taking TRADENAME™.

- **Low blood pressure.** This can make you feel dizzy if you get up too fast from sitting or lying down.

The common side effects with TRADENAME™ are nausea, dizziness, vomiting, sleepiness, and itching.

Constipation is a common side effect of all opioid medicines. Talk to your doctor about the use of laxatives and stool softeners to prevent or treat constipation while taking TRADENAME™.

Tell your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects of TRADENAME™. For a complete list, ask your doctor or pharmacist.

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

How should I store TRADENAME™?

- Store TRADENAME™ at 59°F to 86°F (15°C to 30°C). Keep TRADENAME™ tablets dry.
- Dispose of TRADENAME™ tablets you no longer need.

Keep TRADENAME™ in a safe place out of the reach of children.

General information about TRADENAME™

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRADENAME™ for a condition for which it was not prescribed. **Do not give TRADENAME™ to other people, even if they have the same symptoms you have. Sharing TRADENAME™ could be harmful and is against the law.**

This Medication Guide summarizes the most important information about TRADENAME™. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about TRADENAME™ that is written for doctors. For more information about TRADENAME™ call 1-800-526-7736.

What are the ingredients in TRADENAME™?

Active Ingredient: tapentadol

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, povidone, magnesium stearate, and Opadry® II, a proprietary film-coating mixture containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and aluminum lake coloring.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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