

Palmetto State Pharmaceuticals

Patient Drug Education

TRAMADOL HCL-ACETAMINOPHEN TAB

USES:

This combination medication is used to treat short-term pain (5 days or fewer). Acetaminophen works by blocking or reducing the feeling of pain. It can also reduce a fever. Tramadol belongs to a class of drugs known as opioid analgesics. It works on a part of the brain to block or reduce the feeling of pain. It may also change the balance of some natural chemicals in your body (norepinephrine and serotonin), an effect that may help reduce pain.

HOW TO TAKE THIS MEDICATION:

HOW TO USE: Take this medication by mouth with or without food, usually every 4 to 6 hours as needed or as directed by your doctor. Do not take more than 8 tablets in a 24-hour period. Dosage is based on your medical condition and response to therapy. This medication contains acetaminophen. Do not take more acetaminophen than recommended. (See Side Effects section.) This medication may cause dependence, especially if it has been used regularly for an extended time (more than a few weeks) or if it has been used in high doses. In such cases, if you suddenly stop this drug, withdrawal reactions may occur. Such reactions can include anxiety, sweating, difficulty sleeping, shaking (tremors), diarrhea, and rarely hallucinations. Report any such reactions to your doctor immediately. When stopping extended, regular treatment with this drug, gradually reducing the dosage as directed will help prevent withdrawal symptoms. Consult your doctor or pharmacist for more details. Though it is very unlikely to occur, this medication can also result in abnormal drug-seeking behavior (addiction/habit forming). Do not increase your dose, take it more frequently, or use it for a longer time than prescribed. Properly stop the medication when so directed. This will lessen the chances of becoming addicted. When used for an extended period, this medication may not work as well and may require different dosing. Talk with your doctor if this medication stops working well. Inform your doctor if your condition persists or worsens.

SIDE EFFECTS:

Drowsiness, constipation, upset stomach, nausea, diarrhea, dizziness, headache, or dry mouth may occur. If any of these effects persist or worsen, notify your doctor. Remember that your doctor has prescribed this medication because the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes (e.g., nervousness, anxiety, irritability, confusion), trouble sleeping, muscle weakness, shaking (tremor), uncoordinated movements, hot flashes, loss of appetite, vomiting, unusual weight loss, increased sweating, trouble urinating (males only). Tell your doctor immediately if any of these rare but very serious side effects occur: fast/pounding/irregular heartbeat, chest pain, severe headache, blurred vision, fainting, trouble swallowing, ringing in the ears, black stools, vomit that looks like coffee grounds, hallucinations, seizures. If you do not have liver problems, the adult maximum dose of acetaminophen is 4 grams per day (4000 milligrams). If you take more than the maximum daily amount, it may cause serious (possibly fatal) liver disease. Tell your doctor immediately if you have any of the following symptoms of liver damage: stomach/abdominal pain, severe nausea, yellowing eyes/skin, dark urine, extreme tiredness. If you have liver problems, consult your doctor or pharmacist for a safe dosage of this medication. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS:

Before taking this medication, tell your doctor or pharmacist if you are allergic to it; or to other opioids (e.g., codeine); or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney/liver problems, heart problems (e.g., angina, irregular heartbeat), breathing problems (e.g., emphysema, sleep apnea), diabetes, drug or alcohol dependency, a certain seizure disorder (epilepsy), difficulty urinating (e.g., due to an enlarged prostate), recent head injury. This drug may make you dizzy or drowsy; use caution while engaging in activities requiring alertness such as driving or using machinery. To minimize dizziness and lightheadedness, get up slowly from a sitting or lying position. Avoid alcoholic beverages. Daily use of alcohol, especially when combined with acetaminophen, may increase your risk for liver damage. Consult your doctor or pharmacist for more details. The elderly may be more sensitive to the effects of the drug, especially drowsiness and confusion. This medication is not recommended for use during pregnancy. It may harm an unborn baby. Infants born to mothers who have used this drug during pregnancy may have serious problems such as seizures, irritability, abnormal/persistent crying, vomiting, diarrhea. Consult your doctor for more details. This drug passes into breast milk. Because of the possible risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: narcotic pain medications (e.g., codeine), medicine for sleep or anxiety (e.g., zolpidem, alprazolam, diazepam), muscle relaxants (e.g., cyclobenzaprine), antidepressants (e.g., amitriptyline, fluoxetine, paroxetine, trazodone), antihistamines (e.g., promethazine, diphenhydramine), MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, selegiline, tranylcypromine), psychiatric medicines (e.g., chlorpromazine, fluphenazine, thioridazine, risperidone), warfarin, quinidine, digoxin, carbamazepine, sibutramine. Tell your doctor or pharmacist if you take other drugs that may increase your risk of seizures such as: adrenalin-like drugs (e.g., amphetamine, methylphenidate), bupropion, theophylline, caffeine, isoniazid, donepezil, tacrine. Acetaminophen is an ingredient in many nonprescription products and in some combination prescription medications. Read the labels carefully before taking other pain relievers, fever reducers, or

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cold products to see if they also contain acetaminophen. Consult your pharmacist if you are uncertain whether your other prescription or nonprescription products contain acetaminophen. (See also Side Effects section.) Check the labels on all your medicines (e.g., cough-and-cold products) because they may contain drowsiness-causing ingredients. Ask your pharmacist about the safe use of these products.

NOTES:

Do not share this medication with others. It is against the law. Laboratory and/or medical tests should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

MISSED DOSE:

Not applicable.

STORAGE:

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.