

Rx **ALTRAM**
(It is tramadol hydrochloride tablets)



ALTRAM (tramadol hydrochloride tablets) is a centrally acting analgesic. Tramadol hydrochloride is a white, bitter, crystalline and odorless powder. It is readily soluble in water and ethanol. Inactive ingredients in the tablets are corn starch, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sodium starch glycolate, titanium dioxide and wax.

INDICATIONS

ALTRAM is indicated for the management of moderate to moderately severe pain in adults.

DOSAGE AND ADMINISTRATION

Adults (17 years of age and over)

For patients with moderate to moderately severe chronic pain not requiring rapid onset of analgesic effect, the tolerability of ALTRAM can be improved by initiating therapy with the following titration regimen: ALTRAM should be started at 25 mg/day qAM and titrated in 25 mg increments as separate doses every 3 days to reach 100 mg/day (25 mg q.i.d.). Thereafter the total daily dose may be increased by 50 mg as tolerated every 3 days to reach 200 mg/day (50 mg q.i.d.). After titration, ALTRAM 50 to 100 mg can be administered as needed for pain relief every 4 to 6 hours not to exceed 400 mg/day.

For the subset of patients for whom rapid onset of analgesic effect is required and for whom the benefits outweigh the risk of discontinuation due to adverse events associated with higher initial doses, ALTRAM 50 mg to 100 mg can be administered as needed for pain relief every four to six hours, not to exceed 400 mg per day.

USES

This medication is used to relieve moderate pain. It is similar to narcotic pain medications. It works on certain nerves in the brain that control how you experience pain.

CONTRAINDICATIONS

ALTRAM should not be administered to patients who have previously demonstrated hypersensitivity to tramadol, any other component of this product or opioids. ALTRAM is contraindicated in any situation where opioids are contraindicated, including acute intoxication with any of the following: alcohol, hypnotics, narcotics, centrally acting analgesics, opioids or psychotropic drugs. ALTRAM may worsen central nervous system and respiratory depression in these patients.

SIDE EFFECTS

Nausea, vomiting, constipation, lightheadedness, dizziness, drowsiness, headache, or weakness may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

To prevent constipation, maintain a diet adequate in fiber, drink plenty of water, and exercise. If you are taking tramadol regularly, it may be useful to start using a laxative right away instead of waiting until you become constipated. Consult your pharmacist for details regarding the correct use of laxatives (e.g., stimulant-type with stool softener).

This medication may rarely cause a very serious condition called serotonin syndrome. The risk increases when this medication is used with certain other drugs (see Drug Interactions section). Seek immediate medical attention if you develop some of the following symptoms: mental/mood changes (such as agitation, hallucinations), unusual restlessness, loss of coordination, fast heartbeat, severe dizziness, unexplained fever, severe nausea/vomiting/diarrhea, twitchy muscles.

PRECAUTIONS

Before using this medication, tell your doctor or pharmacist your medical history, especially of: certain bowel diseases (paralytic ileus), brain disorders (e.g., seizures, increased intracranial pressure), conditions that increase the risk of seizures (e.g., head injury, brain tumors, meningitis, metabolic tajdrug rheumatism disorders, alcohol/drug withdrawal), adrenal gland problem (e.g., Addison's disease), difficulty urinating (e.g., enlarged prostate, urethral narrowing), heart problems (e.g., irregular heartbeat), personal or family history of regular use/abuse of drugs/alcohol, kidney disease, liver disease,

lung diseases (e.g., chronic obstructive pulmonary disease-COPD, hypoxia), disease of the pancreas (e.g., pancreatitis), mental/mood conditions (e.g., major depression, toxic psychosis), a certain spinal problem (kyphoscoliosis), stomach/intestinal problems (e.g., gallbladder disease), underactive thyroid (hypothyroidism).

This drug may make you dizzy or drowsy. Use caution while driving, using machinery, or doing any activity that requires alertness. Avoid alcoholic beverages because they may increase the risk of this drug's side effects.

To reduce dizziness and lightheadedness, get up slowly when rising from a sitting or lying position.

Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, especially slow/shallow breathing and drowsiness.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom.



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