

New Medicine Available For Round-The-Clock Pain

(NAPSA)—More than 50 million Americans suffer from persistent, chronic pain. Chronic pain is a major health problem that results in personal suffering, reduced productivity and substantial health care costs in the United States. A new once-a-day prescription medicine—ULTRAM® ER (tramadol HCl) Extended-Release tablets—is now available for treatment of moderate to moderately severe chronic pain in adults who need around-the-clock pain treatment for an extended period of time.

“Chronic pain affects a large segment of the American population, often requiring physician treatment for persistent pain,” said Dr. Zorba Paster, Clinical Professor of Family Medicine, University of Wisconsin School of

**Chronic Pain:
A Widespread and Costly Problem**

- According to a recent survey conducted by the American Pain Foundation, the majority of American adults (57%) experienced chronic or recurrent pain during the prior year.
—Among those with chronic pain, more than 3 in 5 were in pain for more than a year.
- A recent study in the U.S. found that working adults who experienced absence from work or reduced job performance due to pain lost an average of 4.6 productive hours a week.
- Estimated direct and indirect costs of chronic pain in the United States exceed \$100 billion annually.

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Medicine and Public Health. “ULTRAM ER is an important new option for adults who suffer from moderate to moderately severe chronic pain, and for the

physicians who treat them.”

ULTRAM ER was found in clinical studies to be safe and effective for chronic pain such as from osteoarthritis. Studies have also shown that the pain relief from ULTRAM ER helped improve chronic pain-related sleep problems such as trouble falling asleep or waking up in the middle of the night due to pain.

“There are many options for treating pain and recently there has been a lot of change in the treatment landscape,” said Dr. Paster. “Therefore, it’s important for patients to have a discussion with their health care provider about appropriate options for their individual needs.”

For more information about ULTRAM ER, please visit www.ULTRAM-ER.com.

Important Safety Information: ULTRAM ER is contraindicated in any situation where opioids are contraindicated, including a history of anaphylactoid reactions to opioids, and in patients who have previously demonstrated hypersensitivity to tramadol.

ULTRAM ER must be swallowed whole and must not be chewed, crushed or split. Chewing, crushing or splitting the tablet will result in the uncontrolled delivery of the opioid and could result in overdose and death. This risk is increased with concurrent abuse of alcohol and other substances. Tramadol, like other opioids used in analgesia, can be abused.

Seizures have been reported in patients receiving tramadol. The risk of seizure is increased with doses of tramadol above the recommended range.

Concomitant use of tramadol increases the seizure risk in patients taking tricyclic antidepressants, selective serotonin reuptake inhibitors or other opioids.

Tramadol may enhance the seizure risk in patients taking MAO inhibitors, neuroleptics or other drugs that reduce the seizure threshold.

Risk of convulsions may also increase in patients with epilepsy, those with a history of seizures or in patients with a recognized risk for seizure (such as head trauma, metabolic disorders, alcohol and drug withdrawal and CNS infections).

Do not prescribe ULTRAM ER for patients who are suicidal or addiction-prone.

ULTRAM ER should be used with caution and in reduced dosages when administered to patients receiving CNS depressants such as alcohol, opioids, anesthetic agents, narcotics, phenothiazines, tranquilizers, antidepressants or sedative hypnotics. ULTRAM ER increases the risk of CNS and respiratory depression in these patients.

Administer ULTRAM ER cautiously in patients at risk for respiratory depression. In these patients, non-opioid analgesics should be considered. When large doses of tramadol are administered with anesthetic medications or alcohol, respiratory depression may result. Respiratory depression should be treated as an overdose. If naloxone is to be administered, use cautiously because it may precipitate seizures.

Use ULTRAM ER cautiously in patients over 65 years of age due to the greater frequency of adverse events observed in this population.

ULTRAM ER should not be used in patients with severe renal (CrCl <30 mL/min) or hepatic (Child-Pugh Class C) impairment.

In clinical trials, the most frequently reported side effects in patients receiving ULTRAM ER and placebo, respectively, were dizziness (not vertigo, 15.9 percent-22.5 percent vs. 6.9 percent), nausea (15.1 percent-25.5 percent vs. 7.9 percent), constipation (12.2 percent-21.3 percent vs. 4.2 percent), somnolence (7.3 percent-11.3 percent vs. 1.7 percent) and flushing (7.7 percent-10.0 percent vs. 4.4 percent).

ULTRAM ER should not be administered at a dose exceeding 300 mg per day.