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Kadian (Morphine Sulfate Extended-Release)

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The following serious adverse reactions are discussed elsewhere in the labeling:

-]WARNINGS AND PRECAUTIONS Addiction, Abuse, and Misuse [see
-]WARNINGS AND PRECAUTIONS Life Threatening Respiratory Depression [see
-]WARNINGS AND PRECAUTIONS Neonatal Opioid Withdrawal Syndrome [see
-]WARNINGS AND PRECAUTIONS Interactions with Other CNS Depressants [see
-]WARNINGS AND PRECAUTIONS Hypotensive Effect [see
-]WARNINGS AND PRECAUTIONS Gastrointestinal Effects [see
-]WARNINGS AND PRECAUTIONS Seizures [see

In the randomized study, the most common adverse reactions with KADIAN therapy were drowsiness, constipation, nausea, dizziness, and anxiety. The most common adverse reactions leading to study discontinuation were nausea, constipation (may be severe), vomiting, fatigue, dizziness, pruritus, and somnolence.

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Percentage %	Clinical trial patients with chronic cancer pain (n=227) (AE by Body System as seen in 2% or more of patients)
28	CENTRAL NERVOUS SYSTEM
9	Drowsiness
6	Dizziness
5	Anxiety
4	Confusion
3	Dry mouth
2	Tremor
26	GASTROINTESTINAL
9	Constipation
7	Nausea
3	Diarrhea
3	Anorexia
3	Abdominal pain
2	Vomiting
16	BODY AS A WHOLE
3	Pain
3	Disease progression
2	Chest pain
2	Diaphoresis
2	Fever
2	Asthenia
2	Accidental injury
3	RESPIRATORY
3	Dyspnea
3	SKIN & APPENDAGES
3	Rash
3	METABOLIC & NUTRITIONAL
3	Peripheral edema
4	HEMIC & LYMPHATIC
2	Anemia

In clinical trials in patients with chronic cancer pain, the most common adverse events reported by patients at least once during therapy were drowsiness (9%), constipation (9%), nausea (7%), dizziness (6%), and anxiety (6%). Other less common side effects expected from KADIAN or seen in less than 2% of patients in the clinical trials were:

- Headache, chills, flu syndrome, back pain, malaise, withdrawal syndrome **Body as a Whole:** •
- Tachycardia, atrial fibrillation, hypotension, hypertension, pallor, facial flushing, palpitations, bradycardia, syncope **Cardiovascular:** •
- Confusion, anxiety, abnormal thinking, abnormal dreams, lethargy, depression, loss of concentration, insomnia, amnesia, **Central Nervous System:** •
- paresthesia, agitation, vertigo, foot drop, ataxia, hypesthesia, slurred speech, hallucinations, vasodilation, euphoria, apathy, seizures, myoclonus
- Hyponatremia due to inappropriate ADH secretion, gynecomastia **Endocrine:** •
- Dysphagia, dyspepsia, stomach atony disorder, gastro-esophageal reflux, delayed gastric emptying, biliary colic **Gastrointestinal:** •
- Thrombocytopenia **Hemic and Lymphatic:** •
- Hyponatremia, edema **Metabolic and Nutritional:** •
- Back pain, bone pain, arthralgia **Musculoskeletal:** •
- Hiccup, rhinitis, atelectasis, asthma, hypoxia, respiratory insufficiency, voice alteration, depressed cough reflex, non-cardiogenic **Respiratory:** •
- pulmonary edema
- Decubitus ulcer, pruritus, skin flush **Skin and Appendages:** •
- Amblyopia, conjunctivitis, miosis, blurred vision, nystagmus, diplopia **Special Senses:** •
- Urinary abnormality, amenorrhea, urinary retention, urinary hesitancy, reduced libido, reduced potency, prolonged labor **Urogenital:** •

Four-Week Open-Label Safety Study

In the open-label, 4-week safety study, 1418 patients ages 18 to 85 with chronic, non-malignant pain (e.g., back pain, osteoarthritis, neuropathic pain) were enrolled. The most common adverse events reported at least once during therapy were constipation (12%), nausea (9%), and somnolence (3%). Other less common side effects occurring in less than 3% of patients were vomiting, pruritus, dizziness, sedation, dry mouth, headache, fatigue, and rash.

Post-Marketing Experience

Anaphylaxis has been reported with ingredients contained in KADIAN. Advise patients how to recognize such a reaction and when to seek medical attention.