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Avinza (Morphine Sulfate)

??? ??????: 30 ?????2/????? 2017

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

The most common adverse reactions with AVINZA include constipation, nausea 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.

In controlled and open-label clinical studies, 560 patients with chronic malignant or non-malignant pain were treated with AVINZA. The most common serious adverse events reported with administration of AVINZA were vomiting, nausea, death, dehydration, dyspnea, and sepsis. (Deaths occurred in patients treated for pain due to underlying malignancy.) Serious adverse events caused by morphine include respiratory depression, apnea, and to a lesser degree, circulatory depression, respiratory arrest, shock and cardiac arrest.

The most common adverse events (seen in greater than 10%) reported by patients treated with AVINZA during the clinical trials at least once during therapy were constipation, nausea, somnolence, vomiting, and headache. Adverse events occurring in 5-10% of study patients were peripheral edema, diarrhea, abdominal pain, infection, urinary tract infection, accidental injury, flu syndrome, back pain, rash, sweating, fever, insomnia, depression, paresthesia, anorexia, dry mouth, asthenia and dyspnea. Other less common side effects expected from opioid analgesics, including morphine, or seen in fewer than 5% of patients taking AVINZA in the clinical trials were:

malaise, withdrawal syndrome. **Body as a Whole:**

bradycardia, hypertension, hypotension, palpitations, syncope, tachycardia. **Cardiovascular System:**

biliary pain, dyspepsia, dysphagia, gastroenteritis, abnormal liver function tests, rectal disorder, thirst. **Digestive System:**

anemia, thrombocytopenia. **Hemic and Lymphatic System:**

edema, weight loss. **Metabolic and Nutritional Disorders:**

skeletal muscle rigidity. **Musculoskeletal:**

abnormal dreams, abnormal gait, agitation, amnesia, anxiety, ataxia, confusion, convulsions, coma, delirium, euphoria, hallucinations, lethargy, **Nervous System:** nervousness, abnormal thinking, tremor, vasodilation, vertigo.

hiccup, hypoventilation, voice alteration. **Respiratory System:**

dry skin, urticaria. **Skin and Appendages:**

amblyopia, eye pain, taste perversion. **Special Senses:**

abnormal ejaculation, dysuria, impotence, decreased libido, oliguria, urinary retention. **Urogenital System:**

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

