AVINZA®—NEW dosing strengths now available

The once-daily, 24-hour pain relief now offers greater dosing flexibility

- AVINZA® is now available in **45-mg** and **75-mg** capsules
- New strengths allow for more precise dosing during opioid conversion and titration
- Dosage may be titrated as often as every other day in opioid-tolerant patients

Give them around-the-clock relief with AVINZA®

- Continuous 24-hour pain relief[1]
- Sustained plasma concentrations for sustained relief[1]
  – Steady-state plasma concentrations achieved in 48 to 72 hours
- Once-daily dosing may facilitate compliance with the prescribed dosing regimen[2]
- Efficacy demonstrated in a wide range of patients: osteoarthritis; low-back pain; and chronic, noncancer pain[2-4]
- **NOT** for use as a prn analgesic
- AVINZA® is not indicated for postoperative use

Now Available in More Dosing Strengths for Your Convenience

Supplied dosage	30 mg Bottles of 100 capsules	45 mg Bottles of 100 capsules	60 mg Bottles of 100 capsules	75 mg Bottles of 100 capsules	90 mg Bottles of 100 capsules	120 mg Bottles of 100 capsules
NDC #	NDC 60793-605-01	NDC 60793-603-01	NDC 60793-606-01	NDC 60793-604-01	NDC 60793-607-01	NDC 60793-608-01

Capsules shown at actual size.

Indications

- AVINZA® (morphine sulfate extended-release capsules) is a modified-release formulation of morphine sulfate indicated for once-daily administration for the relief of moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time
- AVINZA® is NOT intended for use as a prn analgesic
  (See additional information regarding indications on back page)

IMPORTANT SAFETY INFORMATION

- **AVINZA® capsules must be swallowed whole or the contents of the capsules sprinkled on applesauce. The capsule beads must not be chewed, crushed, or dissolved due to the risk of rapid release and absorption of a potentially fatal dose of morphine**
- **Patients must not consume alcoholic beverages or use prescription or nonprescription medications containing alcohol while on AVINZA® therapy due to the risk of the rapid release and absorption of a potentially fatal dose of morphine**

Please see additional Important Safety Information on back page

or Click Here for Full Prescribing Information.

24 hour
AVINZA®
(morphine sulfate extended-release capsules)

Important Safety Information

Indications (contd)

- The safety and efficacy of using AVINZA® in a postoperative setting has not been evaluated. AVINZA® is not indicated for postoperative use. If the patient has been receiving the drug prior to surgery, resumption of the presurgical dose may be appropriate once the patient is able to take the drug by mouth. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate. (See American Pain Society guidelines.)

IMPORTANT SAFETY INFORMATION (contd)

- Morphine sulfate is a Schedule II controlled substance that can be abused in a manner similar to other legal or illegal opioids
- AVINZA® is contraindicated in patients with known hypersensitivity to morphine, morphine salts, or any components of the product
- AVINZA®, like all opioids, is contraindicated in patients with respiratory depression (in the absence of resuscitative equipment), acute or severe bronchial asthma, and known or suspected paralytic ileus
- Use only with extreme caution in patients with chronic obstructive pulmonary disease or cor pulmonale, pre-existing respiratory depression, and in patients with substantially decreased respiratory reserve. In such patients, usual therapeutic doses may result in apnea
- AVINZA® should be administered cautiously and in reduced dosages in patients with severe renal or hepatic insufficiency, Addison's disease, hypothyroidism, prostatic hypertrophy, or urethral stricture, and in elderly or debilitated patients
- **Dosing**
  - **The daily dose of AVINZA® must be limited to a maximum of 1600 mg/day. Doses of AVINZA® over 1600 mg/day contain a quantity of fumaric acid that may result in serious renal toxicity**
  - **The 45-mg, 60-mg, 75-mg, 90-mg, and 120-mg capsules are for use in opioid-tolerant patients only.** When the patient no longer requires therapy with AVINZA®, doses should be tapered gradually to prevent signs and symptoms of withdrawal in the physically dependent patient
- **Adverse events**
  - The most common serious adverse events reported during clinical studies with AVINZA® were vomiting, nausea, death (in patients treated for pain due to underlying malignancy), dehydration, dyspnea, and sepsis
  - Additional common adverse events reported during clinical studies include constipation, somnolence, and headache
  - Serious adverse events caused by morphine include respiratory depression, apnea, and to a lesser degree, circulatory depression, respiratory arrest, shock, and cardiac arrest

Please Click Here for Full Prescribing Information.

References: 1. Avinza [package insert]. Bristol, TN: King Pharmaceuticals, Inc; 2008. **2.** Rauck RL, Bookbinder SA, Bunker TR, et al. The ACTION study: a randomized, open-label, multicenter trial comparing once-a-day extended-release morphine sulfate capsules (AVINZA®) to twice-a-day controlled-release oxycodone hydrochloride tablets (OxyContin®) for the treatment of chronic, moderate to severe low back pain. *J Opioid Manag.* 2006;2(3):155-166. **3.** Caldwell JR, Rapoport RJ, Davis JC, et al; for the Avinza™ TRG004-04 Study Group. Efficacy and safety of a once-daily morphine formulation in chronic, moderate-to-severe osteoarthritis pain: results from a randomized, placebo-controlled, double-blind trial and an open-label extension trial. *J Pain Symptom Manage.* 2002;23(4):278-291. **4.** Adams EH, Chwiecko P, Ace-Wagoner Y, et al. A study of AVINZA® (morphine sulfate extended-release capsules) for chronic moderate-to-severe noncancer pain conducted under real-world treatment conditions—the ACCPT study. *Pain Pract.* 2006;6(4):254-264.

King Pharmaceuticals

Please visit us at www.avinza.com.
www.kingpharm.com

24 hour
AVINZA® II
(morphine sulfate extended-release capsules)