

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

## QD dosing for continuous 24-hour analgesia

### GOALS

- Provide continuous, around-the-clock pain relief
- Improve physical and social functioning<sup>1</sup>
- Simplify drug accountability

### INDICATIONS AND USAGE

AVINZA® capsules are a modified-release formulation of morphine sulfate intended for once-daily administration indicated for the relief of moderate to severe pain requiring continuous, around-the-clock opioid therapy for an extended period of time.

### PRODUCT DESCRIPTION





AVINZA® capsules 30, 60, 90, and 120 mg contain both immediate-release and extended-release beads of morphine sulfate. AVINZA® uses the proprietary SODAS® (Spheroidal Oral Drug Absorption System) to achieve the desired release characteristics in the gastrointestinal tract, enabling AVINZA® to provide continuous, 24-hour pain relief with once-daily dosing.

### DOSING

Once daily (QD)

### STORAGE

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F). See USP Controlled Room Temperature. Protect from light and moisture. Dispense in a tight, light-resistant container as defined in USP.

Supplied Dosage	30 mg bottles of 100 capsules 	60 mg bottles of 100 capsules 	90 mg bottles of 100 capsules 	120 mg bottles of 100 capsules 
NDC#	NDC 60793-605-01	NDC 60793-606-01	NDC 60793-607-01	NDC 60793-608-01
Wholesale Acquisition Cost*	\$293.00 per bottle	\$563.75 per bottle	\$855.51 per bottle	\$1,000.15 per bottle

Please see reverse side for Important Safety Information.



## Meet your goals with continuous 24-hour analgesia

Significant improvement in physical and social functioning<sup>1,2</sup>

### Once-daily dosing

- The QD extended-release opioid for moderate to severe pain

### Simplified accountability

- 30 days = 30 doses

<sup>1</sup>Compared with baseline.

AVINZA<sup>®</sup> (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.

### Important Safety Information

**AVINZA<sup>®</sup> capsules are to be swallowed whole or the contents of the capsules sprinkled on applesauce. The capsule beads are not to 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 while on AVINZA<sup>®</sup> therapy. Additionally, patients must not use prescription or nonprescription medications containing alcohol while on AVINZA<sup>®</sup> therapy. Consumption of alcohol while taking AVINZA<sup>®</sup> may result in the rapid release and absorption of a potentially fatal dose of morphine.**

The most common serious adverse events reported with administration of AVINZA<sup>®</sup> capsules were vomiting, nausea, death (in patients treated for pain due to underlying malignancy), dehydration, dyspnea, sepsis, 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. AVINZA<sup>®</sup> is NOT intended for use as a prn analgesic. The safety and efficacy of using AVINZA<sup>®</sup> in a postoperative setting has not been evaluated. AVINZA<sup>®</sup> is not indicated for postoperative use. If the patient has been receiving the drug prior to surgery, resumption of the pre-surgical 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.) Morphine sulfate is a Schedule II controlled substance that can be abused in a manner similar to other legal or illegal opioids.

AVINZA<sup>®</sup> is contraindicated in patients with known hypersensitivity to morphine, morphine salts, or any components of the product. AVINZA<sup>®</sup>, 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<sup>®</sup> 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.

**The daily dose of AVINZA<sup>®</sup> capsules must be limited to a maximum of 1600 mg/day. AVINZA<sup>®</sup> doses over 1600 mg/day contain a quantity of fumaric acid that may result in serious renal toxicity.**

**The 60-mg, 90-mg, and 120-mg capsules are for use in opioid-tolerant patients only.** When the patient no longer requires therapy with AVINZA<sup>®</sup> capsules, doses should be tapered gradually to prevent signs and symptoms of withdrawal in the physically dependent patient.

**Please see accompanying full Prescribing Information.**

SODAS<sup>®</sup> is a registered trademark of Eitan Corporation.

**References:** 1. Rauck RL, Bookbinder SA, Bunker TR, et al. A randomized, open-label, multicenter trial comparing once-a-day AVINZA<sup>®</sup> (morphine sulfate extended-release capsules) versus twice-a-day Oxycotin<sup>™</sup> (oxycodone hydrochloride controlled-release tablets) for the treatment of chronic, moderate to severe low back pain: improved physical functioning in the ACTION trial. *J Opioid Manag.* 2007;3(1):35-43. 2. Data on file. King Pharmaceuticals<sup>®</sup>, Inc.



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