

# OPANA® ER Indication and Important Safety Information

- OPANA ER is indicated for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time
- OPANA ER is not intended for use as an as needed analgesic
- OPANA ER is not indicated for pain in the immediate post-operative period (12–24 hours following surgery) for patients not previously taking opioids because of the risk of oversedation and respiratory depression requiring reversal with opioid antagonists
- OPANA ER is not indicated for pain in the post-operative period if the pain is mild or not expected to persist for an extended period of time

OPANA ER has a boxed warning as follows:

**WARNING: OPANA ER contains oxymorphone, which is a morphine-like opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. Oxymorphone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OPANA ER in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion. OPANA ER is an extended-release oral formulation of oxymorphone indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. OPANA ER is NOT intended for use as an as needed analgesic. OPANA ER TABLETS are to be swallowed whole and are not to be broken, chewed, dissolved, or crushed. Taking broken, chewed, dissolved, or crushed OPANA ER TABLETS leads to rapid release and absorption of a potentially fatal dose of oxymorphone. Patients must not consume alcoholic beverages, or prescription or nonprescription medications containing alcohol, while on OPANA ER therapy. The co-ingestion of alcohol with OPANA ER may result in increased plasma levels and a potentially fatal overdose of oxymorphone.**

- OPANA ER is **contraindicated** in patients with a known hypersensitivity to oxymorphone hydrochloride, morphine analogs such as codeine, or any of the other ingredients of OPANA ER; in patients with moderate or severe hepatic impairment or in any situation where opioids are contraindicated such as: patients with respiratory depression (in the absence of resuscitative equipment or in unmonitored settings), acute or severe bronchial asthma, hypercarbia, and in any patient who has or is suspected of having paralytic ileus



Please see Dosage and Administration on page 4.

# For patients like Mike who need more pain control



**think™ True 12-hour dosing that lasts<sup>1</sup>**

**think™ Demonstrated success with an individualized dose<sup>2</sup>**

In a 12-week trial in 205 *opioid-naïve* patients with moderate to severe chronic low back pain<sup>2</sup>

- **89%** of patients reported a decrease, no change, or a minimal increase ( $\leq 10$  mm) in pain score (VAS\*) over the treatment phase from Day 7 until the end of the study<sup>1</sup>
- **72%** of *opioid-naïve* patients on OPANA ER (n=105) had a  $\geq 50\%$  pain score reduction<sup>1</sup>



Tablets shown are not actual size.

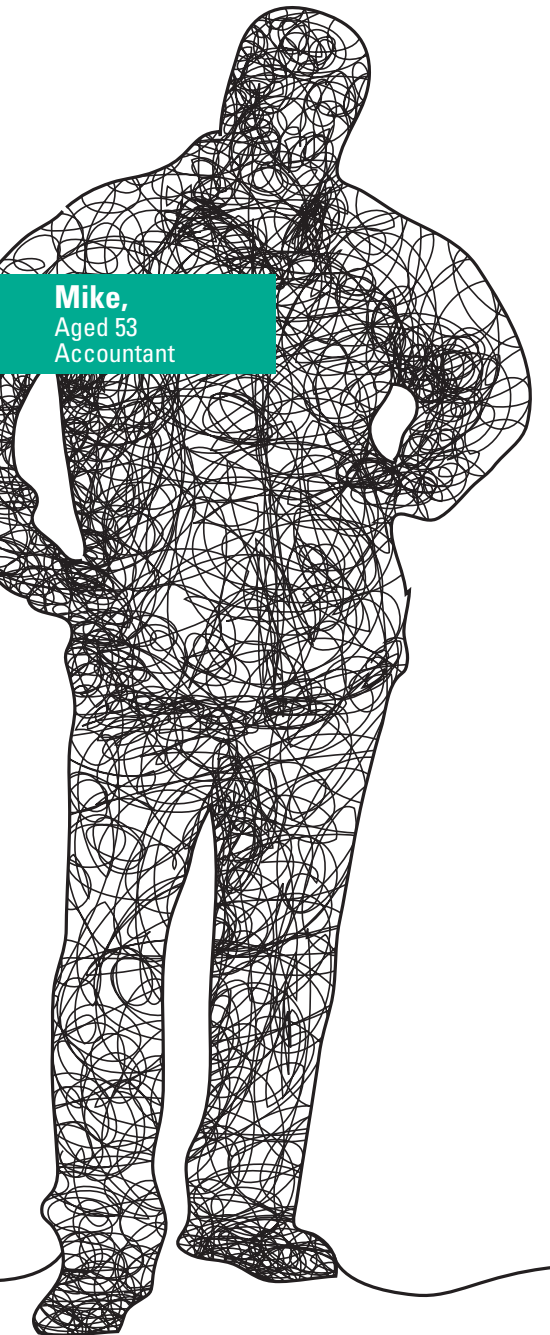
\*Visual analog scale.

**Please see Important Safety Information, including boxed WARNING, on pages 3 and 5, and accompanying full Prescribing Information.**

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 DEA Order Form Required  
 OPANA® is a registered trademark of Endo Pharmaceuticals.  
 think™ is a trademark of Endo Pharmaceuticals.



# Mike needs more pain control to supplement his nonpharmacologic options



**Mike,**  
 Aged 53  
 Accountant

## Patient history

- Ex-football player who has recently developed degenerative disc disease
- Moderate to severe pain has been treated with NSAIDs, including COX-2 inhibitors, and acetaminophen
- Has never been treated with an opioid

## Ibuprofen and physical therapy are not enough

- Treatment with 800 mg ibuprofen every 6 hours has become ineffective as the pain has progressed
- Pain score range: 4–7 out of 10
- Physical therapy twice a week helps increase flexibility and range of motion

## Current chronic pain management plan needs revision

## Managing the complexities of moderate to severe chronic pain?

## Initiate OPANA® ER in an opioid-naïve patient and titrate to effective pain control

### Mike's new pain management plan

- Healthcare professional has determined patient is appropriate for continuous, around-the-clock opioid therapy

**Step 1:** Start therapy with 5 mg OPANA ER every 12 hours for 2 days

- Starting with 5 mg is a suggested approach

**Step 2:** Titrate by increments of 5–10 mg every 12 hours every 3–7 days until adequate pain relief and acceptable side effects have been achieved

- Patients should be titrated to generally mild or no pain with regular use of no more than 2 doses of supplemental analgesia (ie, "rescue") per 24 hours

- These dosing recommendations should only be considered as suggested approaches to what is actually a series of clinical decisions over time in the management of each individual patient

- OPANA ER should be administered on an empty stomach at least 1 hour prior to or 2 hours after eating

- OPANA ER offers flexible titration and dosing with seven tablet strengths: 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg



Mike is a hypothetical OPANA ER patient; individual results may vary.

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## OPANA® ER: dosage and administration

### Initial dose selection

In the selection of the initial dose of OPANA ER, attention should be given to the following:

- The total daily dose, potency, and specific characteristics of the opioid the patient has been taking previously
- The relative potency estimate used to calculate the equivalent oxymorphone dose needed
- The patient's degree of opioid tolerance
- The age, general condition, and medical status of the patient
- Concurrent nonopioid analgesic and other medications
- The type and severity of the patient's pain
- The balance between pain control and adverse experiences
- Risk factors for abuse, addiction, or diversion, including a prior history of abuse, addiction, or diversion

### Individualization of therapy

- As with any opioid drug product, it is necessary to adjust the dosing regimen for each patient individually, taking into account the patient's prior analgesic treatment experience
- Physicians should individualize treatment in every case, using nonopioid analgesics, as needed opioids and/or combination products, and chronic opioid therapy in a progressive plan of pain management such as outlined by the World Health Organization, the American Pain Society, and the Federation of State Medical Boards Model Guidelines
- Healthcare professionals should follow appropriate pain management principles of careful assessment and ongoing monitoring

### Cessation

- OPANA ER should not be abruptly discontinued. When the patient no longer requires therapy with OPANA ER tablets, doses should be tapered gradually to prevent signs and symptoms of withdrawal in the physically dependent patient
- Patients and their families should be instructed to flush any OPANA ER tablets that are no longer needed

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## Important Safety Information, continued

- OPANA ER is not indicated for pain in the immediate post-operative period (the first 12–24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. OPANA ER is only indicated for post-operative use if the patient is already receiving the drug prior to surgery or if the post-operative pain is expected to be moderate or severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate (see American Pain Society guidelines)
- Respiratory depression is the chief hazard of OPANA ER, particularly in elderly or debilitated patients. OPANA ER should be administered with extreme caution to patients with conditions accompanied by hypoxia, hypercapnia, or decreased respiratory reserve such as: asthma, chronic obstructive pulmonary disease or cor pulmonale, severe obesity, sleep apnea syndrome, myxedema, kyphoscoliosis, central nervous system (CNS) depression, or coma
- Patients receiving other opioid analgesics, general anesthetics, phenothiazines or other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) may experience additive effects resulting in respiratory depression, hypotension, profound sedation, or coma
- OPANA ER should be used with caution in elderly and debilitated patients and in patients who are known to be sensitive to CNS depressants, such as those with cardiovascular, pulmonary, renal, or hepatic disease. OPANA ER should be used with caution in patients with mild hepatic impairment and in patients with moderate to severe renal impairment. These patients should be started cautiously with lower doses of OPANA ER while carefully monitoring for side effects
- OPANA ER is not indicated for preemptive analgesia (administration preoperatively for the management of post-operative pain)
- The most common adverse drug reactions ( $\geq 10\%$ ) in all clinical trials for OPANA ER were nausea, constipation, dizziness (excluding vertigo), vomiting, pruritus, somnolence, headache, increased sweating, and sedation
- Patients and their families should be instructed to flush any OPANA ER tablets that are no longer needed

**References:** 1. OPANA® ER Full Prescribing Information. Chadds Ford, Pa: Endo Pharmaceuticals; 2008. 2. Katz N, Rauck R, Ahdieh H, et al. *Curr Med Res Opin.* 2007;23:117-128.

**Please see accompanying full Prescribing Information.**