

Faroxy Faroxy-ER Faroxyphen

Life
Without Pain



Faran Shimi is a pharmaceutical manufacturing company; an affiliate of Golrang Industrial Group (GIG), developing high-quality from the early stages of manufacturing APIs to produce finished products with the most cutting-edge production lines. Faran Shimi has almost offered a complete product portfolio of narcotic analgesics and this basket is expanding promptly to improve quality of life and bring benefits to consumers.

Faroxy-IR

Oxycodone Immediate-Release Tablet 5, 15 & 30mg



Faroxy-ER

Oxycodone Extended-Release Tablet 10, 20 & 40mg



Faroxyphen

Acetaminophen/Oxycodone Tablet 325/5 & 325/10mg



Calculating Total Daily Dose of Faroxy for Safer Dosage

Calculating total daily doses of opioids is important to appropriately and effectively prescribe, manage, and taper opioid medications. Patients prescribed higher opioid dosages are at higher risk of overdose death. The daily dose calculating of new opioid is as follows⁷:

Current opioids	Conversion factor
Codeine	0.15
Hydromorphone	4
hydrocodone	1
Oxymorphone	3
Oxycodone	1.5
Morphine	1
Methadone ^a	
1-20 mg/d	4
21-40 mg/d	8
41-60 mg/d	10
> 61 mg/d	12

Table1- Oral Opioid Analgesic Conversion Factor Table.

a: Methadone conversion factors increase with increasing dose.

$$\text{Total Daily Dose of New Opioid} = \frac{\text{Current Opioid Daily Dose} \times \text{Conversion Factor of Current Opioid}}{\text{Conversion Factor of New Opioid}} \times 75\%$$

* The obtained total daily dose divided by 2 is for FaroxyER and divided by 4 is for FaroxyIR.

* These dose conversions are estimated and cannot account for all individual differences in genetics and pharmacokinetics.⁸

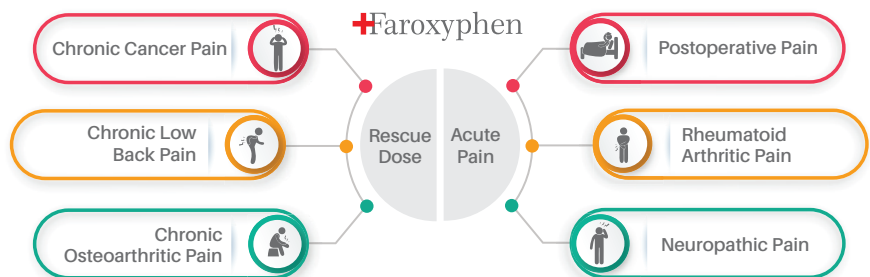
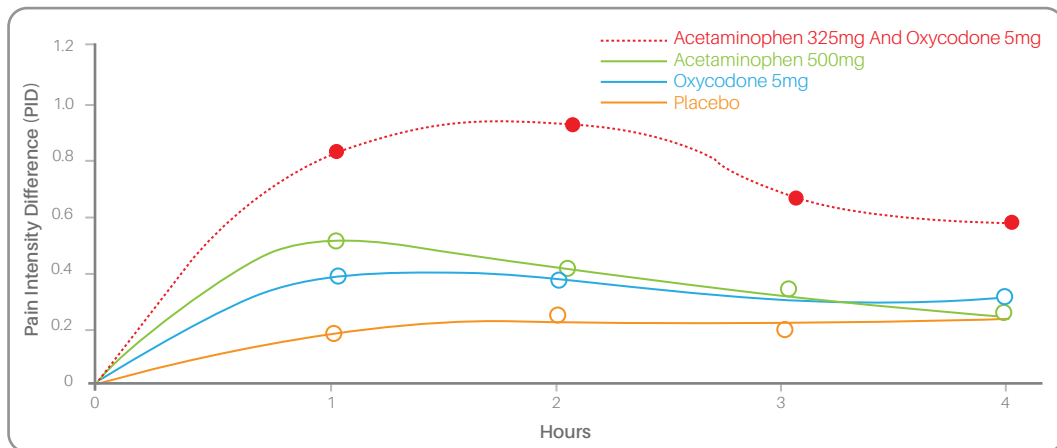
Effective Combination for Add-on Therapy and Rescue Dose⁴

- As an adjuvant therapy if necessary
- As a rescue dose for Break Through Pain (BTP)
- High potency due to its synergistic effect
- Fewer adverse effects

Dosing⁸:	<p>*Initial dose, based on oxycodone content.</p> <p>Infants ≥6 months, Children, and Adolescents: <50kg: 0.1 to 0.2 mg/kg/dose; every 4 to 6 hours as needed. ≥50kg: 5 to 10mg; every 4 to 6 hours as needed.</p> <p>Adults: 5mg (moderate pain) or 10 to 20mg (severe pain); every 4 to 6 hours as needed.</p>
Maximum dose^a	Based on the Acetaminophen content; Do not exceed acetaminophen 4g/day.

a: the maximum daily dose is based on acetaminophen content.

Faroxyphen Offers a Synergistic Mechanism of Action^{5,6}

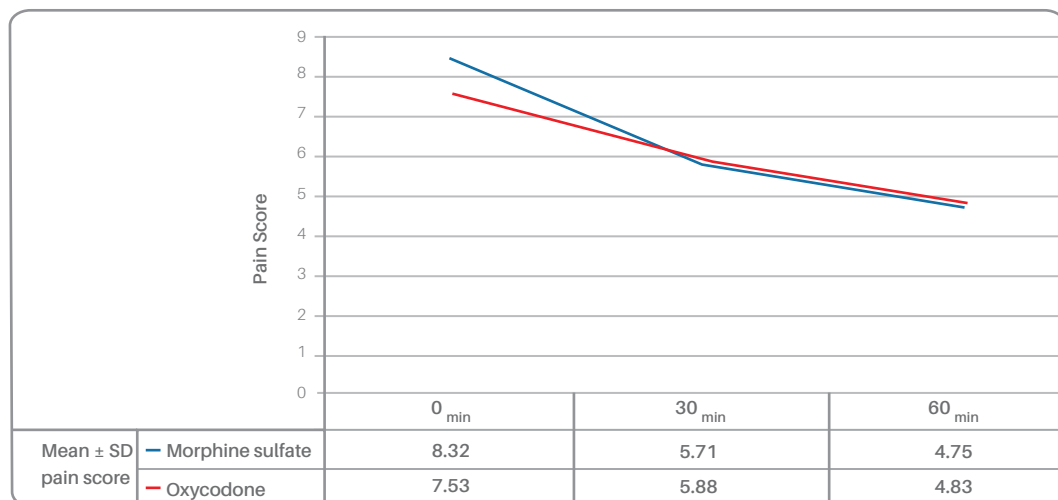


Oxycodone is a semisynthetic opiate partial agonist derived from the opioid alkaloid, thebaine. Oxycodone is used to control moderate to severe pain. The FDA originally approved oxycodone in 1976. It is available as extended release (ER), immediate release tablets (IR), and in combination with acetaminophen. Oxycodone undergoes low first-pass metabolism and has a higher bioavailability (60%-87%) compared with morphine. It is slightly more potent than morphine (Oral Oxycodone is roughly 1.5 times more potent than oral morphine)¹.

Clinical Research

Oral oxycodone is as effective as IV Morphine Sulfate (MS) in management of acute pain following limb trauma²:

Based on clinical trial performed in 2018 there was no **significant** difference between the two groups regarding decrease in pain within the 0, 30 and 60 minutes after administration of either 5mg IV MS or 5mg oral oxycodone. Drowsiness was reported more frequently in MS group after 30 minutes. Eight participants asked for rescue analgesic in MS group, while only one patient asked for more analgesia in oxycodone group. Other adverse effects were similar in both groups.



Faroxy IR | Oxycodone Immediate-Release Tablet

5, 15, 30mg

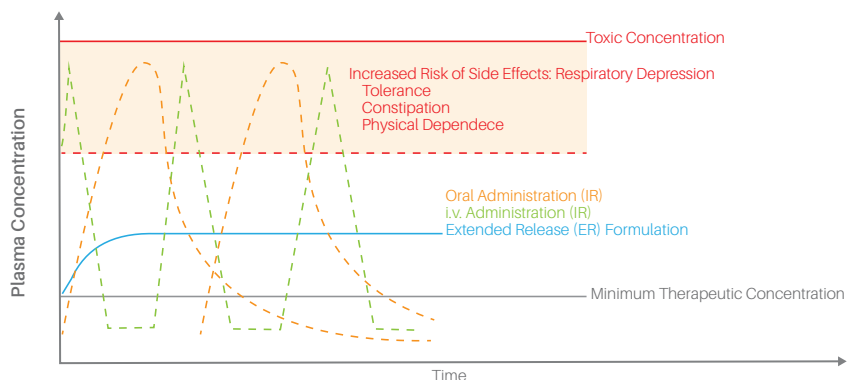
Fast Relief of Acute Pain

- Acute pain relief
- Fast onset of action
- For initial dose in opioid naive patients

Onset	5-15 min
Half Life	3.2, 4 h
Dosing ^a :	<p>Infants ≤6 months: 0.025 to 0.05mg/kg/dose; every 4 to 6 hours as needed.</p> <p>Infants ≥6 months, Children, and Adolescents: <50kg: 0.1 to 0.2 mg/kg/dose; every 4 to 6 hours as needed. ≥50kg: 5 to 10mg; every 4 to 6 hours as needed.</p> <p>Adults: 5 to 15mg; every 4 to 6 hours as needed.</p>
Maximum dose ^a	320mg/day

a: Recommended dose of ER Cap oxycodone base is 288mg/day and 9mg oxycodone based equivalent to 10mg oxycodone hydrochloride.

Oral and IV immediate release formulation; have a duration of action from 3 to 6 hours.



Schematic representation of opioid plasma concentrations in function of the administration route.³

Faroxy-ER

Oxycodone Extended-Release Tablet
10, 20, 40mg

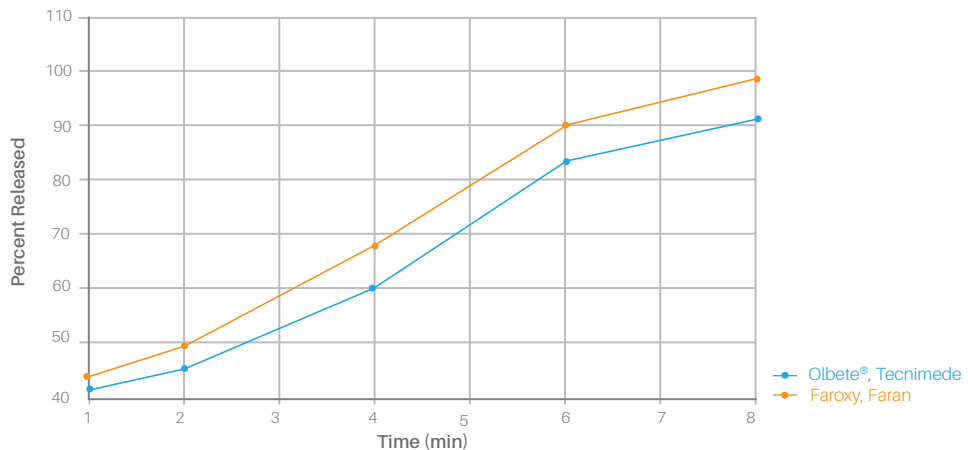
Long Term Opioid Therapy

- Chronic pain relief
- Intermediate onset of action (1 hour)
- Reduction in pill burden
- For long term opioid therapy
- Enhance patient adherence

onset	1 h
Half Life	4.5 h
Dosing ⁸ :	Patients \geq 11 years: 10mg; every 12 hours.
Maximum dose ^a	320mg/day

a: Recommended dose of ER Cap oxycodone base is 288 mg/day and 9mg oxycodone based equivalent to 10mg oxycodone hydrochloride.

Comparative Dissolution Profile of Oxycodone From Test (FAROXY SR. 40mg FC. Tablets, Faran, IRAN) Vs. Reference (Olbete®-SR 40mg FC. Tablets, Tecnimed, Canada) Drugs



Faroxy-ER 40mg (manufactured by FaranShimi pharmaceutical Company) and Olbete®-SR 40mg (manufactured by Tecnimed in Canada) according to FDA guidance for industry entitled "Bioavailability and Bioequivalence studies submitted in NDAs or INDs_General considerations" were bioequivalent. Also, it is worth to remark that this study was approved by Iran Food and Drug Administration.

Contraindications⁸:

- Hypersensitivity to oxycodone or other opioids.
- Patients with circulatory shock and coma.
- Significant respiratory depression, acute or severe bronchial asthma, moderate to severe sleep-disorder breathing.
- Known or suspected paralytic ileus and gastrointestinal obstruction.
- Not recommended during pregnancy and breast feeding.

Warning and Precautions⁸:

- **Use with caution:** in CNS depression, Severe hypotension, Respiratory depression, Seizures, Constipation, Mental health conditions, Obesity, Thyroid dysfunction, Adrenal insufficiency, Prostatic hyperplasia/urinary stricture, Acute alcoholism, Underlying GI disorders, Difficulty in swallow, Pancreatic and Biliary disease, Head trauma, Hepatic and renal impairment, G6PD deficiency.
- **Cytochrome P450 3A4 interactions:** The concomitant use of oxycodone with all CYP3A4 inhibitors and discontinuation of a concomitantly used CYP3A4 inducer may result in an increase in oxycodone plasma concentrations.
- **Hepatotoxicity:** Most of the cases of liver injury are associated with the use of Acetaminophen at doses that exceed 4g/day in adults.
- **Skin reactions:** Discontinue therapy at the first appearance of skin rash.

Side Effect⁸ (> 10%):

Drowsiness, Headache, Dizziness, Pruritus, Nausea, Constipation, Vomiting, Fever, Xerostomia.

Drug Interactions⁸:

- CNS depressants
- Opioids (Mixed Agonist / Antagonist)
- Anticholinergic Agents
- CYP3A4 inducer and inhibitors
- Diuretics
- Serotonergic Agents

Reference:

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5. Gatti, Antonio et al. "Oxycodone/paracetamol: a low-dose synergic combination useful in different types of pain." *Clinical drug investigation*
6. Raffa, R B et al. "Oxycodone combinations for pain relief." *Drugs of today (Barcelona, Spain: 1998)* vol. 46, 6 (2010): 379-98. doi:10.1358/dot.2010.46.6.1470106.
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8. Uptodate/oxycodone/2022.