

Introducing an **important advance** in pain relief...

NEW
ACUROX[®]
(oxycodone HCl, USP and niacin, USP) tablets 

Now Available

The first immediate-release oxycodone with “triple action” Aversion[®] Technology

Aversion[®] Technology is a patented composition of active and inactive ingredients intended to relieve moderate to severe pain and deter common methods of prescription drug abuse, including intravenous injection of dissolved tablets, nasal snorting of crushed tablets, and intentional swallowing of excess numbers of tablets.

Surfactants form a white, foamy substance that contributes to drug disliking if crushed tablets are inhaled or snorted.¹

Surfactants

Functional excipients turn dissolved tablets into a thick, gelatinous mixture that impedes chemical extraction of oxycodone and is difficult to draw into a syringe.¹

Functional excipients

Niacin

Niacin, a well-known nutritional supplement, produces unpleasant flushing if taken at higher-than-recommended doses.¹

ACUROX[®], a Schedule II controlled substance, contains oxycodone HCl, an opioid agonist with an abuse liability similar to morphine.

ACUROX[®] is indicated for the relief of moderate to severe pain where the use of an immediate-release, orally administered, opioid analgesic tablet is appropriate.

The most frequent adverse reactions in patients receiving ACUROX[®] were consistent with the known adverse reactions for oxycodone and niacin and were nausea, vomiting, dizziness, pruritus, and flushing.

Although ACUROX[®] has been designed to minimize the potential risk of nonmedical and unintended oxycodone use, ACUROX[®] cannot make any claims related to misuse, abuse, and diversion of opioids.

“Aversion[®] Technology” is not intended to imply an indication or a claim, but, rather, is a general description of agents with the potential to address the misuse, abuse, and diversion of opioids.

Please see Important Safety Information, including full Indication, on page 3 and accompanying full Prescribing Information.



Patient Counseling Information

Patients receiving ACUROX[®] or their caregivers should be given the following information:

Ingredients in ACUROX[®]

- Patients should be advised that ACUROX[®] contains oxycodone, a morphine-like pain reliever, and niacin
- Patients should notify their physician if they are taking lipid-lowering drugs containing niacin, or vitamins/nutritional supplements containing niacin or nicotinamide

Improper Use

- Patients should be cautioned that ingestion of more than the recommended dose of ACUROX[®] may result in undesirable niacin-induced effects, such as: skin flushing, intense feelings of warmth, itching, chills and headache
- Concurrent consumption of alcohol and hot drinks with ACUROX[®] may increase side effects such as flushing and pruritus (see Section 16.6 of the accompanying full Prescribing Information for additional information)

Patients With Diabetes

- Patients with diabetes should notify their physician of changes in blood glucose values

Effects During Pregnancy and Breastfeeding

- ACUROX[®] should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing mothers should not use ACUROX[®]

Storage and Disposal

- Patients should be instructed to keep ACUROX[®] in a secure place out of the reach of children. They should protect it from theft, and it should never be given to anyone other than the individual for whom it was prescribed

Respiratory depression is the chief hazard of all opioid agonists, particularly in elderly or debilitated patients. ACUROX[®] 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, CNS depression or coma.

The safety and efficacy of ACUROX[®] in individuals less than 18 years of age have not been evaluated.

Important Safety Information

ACUROX[®] is indicated for the relief of moderate to severe pain where the use of an immediate-release, orally administered, opioid analgesic tablet is appropriate.

ACUROX[®], a Schedule II controlled substance, contains oxycodone HCl, an opioid agonist with an abuse liability similar to morphine.

Oxycodone may have additive effects when used in conjunction with alcohol, other opioids, or illicit drugs that cause central nervous system (CNS) depression. When oxycodone is used in combination with these drugs, respiratory depression, hypotension, and profound sedation or coma may result. ACUROX[®] should be used with caution in patients who consume substantial quantities of alcohol and/or have a past history of liver disease.

Respiratory depression is the chief hazard of all opioid agonists, particularly in elderly or debilitated patients. ACUROX[®] 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, CNS depression or coma.

ACUROX[®] may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using this drug should be cautioned accordingly.

In a patient physically dependent on opioids, when the patient no longer requires analgesic therapy, doses of ACUROX[®] should be tapered gradually to minimize signs and symptoms of opioid withdrawal.

ACUROX[®] should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing mothers should not use ACUROX[®].

The safety and efficacy of ACUROX[®] in individual less than 18 years of age have not been evaluated.

ACUROX[®] should be used with caution in elderly and debilitated patients.

Patients should be instructed to keep ACUROX[®] in a secure place out of the reach of children. They should protect it from theft, and it should never be given to anyone other than the individual for whom it was prescribed.

A dose of ACUROX[®] greater than 2 tablets every 6 hours is not recommended due to the possibility of inducing undesirable niacin effects such as cutaneous flushing, intense feelings of warmth, pruritus, chills and headache.

ACUROX[®] is contraindicated in patients with a known hypersensitivity to oxycodone, niacin, any of the inactive ingredients, or in any situation where opioids are contraindicated; in patients with respiratory depression (except in monitored settings and in the presence of resuscitative equipment) or in patients with acute or severe bronchial asthma or hypercarbia; in patients who have or are suspected of having paralytic ileus; in patients with active liver diseases or unexplained liver transaminase elevations; active peptic ulcer disease; or arterial bleeding.

Adverse events

The most frequent adverse reactions in patients receiving ACUROX[®] were consistent with the known adverse reactions for oxycodone and niacin and were nausea, vomiting, dizziness, pruritus, and flushing.

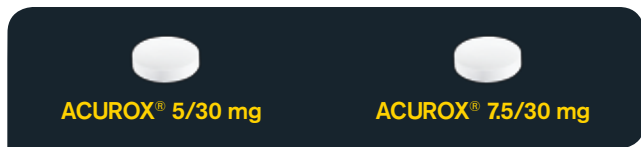
Please see accompanying full Prescribing Information.

NEW
ACUROX[®]
 (oxycodone HCl, USP and niacin, USP) tablets 

Now Available

The first immediate-release oxycodone with “triple action” Aversion[®] Technology

Available in 2 strengths



Tablets shown are not the actual size.

- As with other opioids, dosing should be individualized to achieve adequate pain relief
 - Dosing may be initiated at 1 or 2 tablets every 6 hours^a
- Protect from moisture
 - Exposure to water can damage ACUROX[®] Tablets



ACUROX[®] 5/30 mg
 (5 mg oxycodone HCl/30 mg niacin)



ACUROX[®] 7.5/30 mg
 (7.5 mg oxycodone HCl/30 mg niacin)

NDC #

TK

TK

WAC^b

\$XX/bottle of 100

\$XX/bottle of 100

^bWholesale acquisition cost.

^a A dose of ACUROX[®] greater than 2 tablets every 6 hours is not recommended.

A dose of ACUROX[®] greater than 2 tablets every 6 hours is not recommended due to the possibility of inducing undesirable niacin effects such as cutaneous flushing, intense feelings of warmth, pruritus, chills and headache.

ACUROX[®] is contraindicated in patients with a known hypersensitivity to oxycodone, niacin, any of the inactive ingredients, or in any situation where opioids are contraindicated; in patients with respiratory depression (except in monitored settings and in the presence of resuscitative equipment) or in patients with acute or severe bronchial asthma or hypercarbia; in patients who have or are suspected of having paralytic ileus; in patients with active liver diseases or unexplained liver transaminase elevations; active peptic ulcer disease; or arterial bleeding.

Reference: 1. Acurox [package insert]. Bristol, TN: King Pharmaceuticals, Inc.; 2009.

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King Pharmaceuticals

www.kingpharm.com

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