**Medication Guide**

Oxymorphone Hydrochloride (ex-4E-MOR-tine HYE-dro-klor-ide) Extended-Release Tablets, for oral use

**Oxymorphone hydrochloride extended-release tablets are:**

- A strong prescription medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require around-the-clock, long-term treatment with an opioid, when other treatment options have not worked. Oxymorphone hydrochloride extended-release tablets may cause you to overuse and become physically dependent on a medicine that can be habit-forming, even after taking it for a short time. Your doctor can prescribe oxymorphone hydrochloride extended-release tablets for you, but only if it is safe for you to take it.

**Tell your healthcare provider if you:**

- Have had a rash or allergic reaction to oxymorphone hydrochloride extended-release tablets.
- Are allergic to any medicine.
- Are pregnant or plan to become pregnant. Oxymorphone hydrochloride extended-release tablets can harm your unborn baby if taken during pregnancy. Tell your doctor if you are pregnant or plan to become pregnant while taking oxymorphone hydrochloride extended-release tablets.
- Are breastfeeding or plan to breastfeed. It is not known whether oxymorphone hydrochloride extended-release tablets pass into breast milk or if they can harm your baby. You and your doctor should decide if you will take oxymorphone hydrochloride extended-release tablets while you are breastfeeding.

**Tell your healthcare provider before you:**

- Take any other medicine, whether over the counter or prescription. You can ask your pharmacist if a new medicine might affect your oxymorphone hydrochloride extended-release tablets.

**If you take oxymorphone hydrochloride extended-release tablets with:**

- Alcohol, sedatives, tranquilizers, or any other medicine that makes you drowsy, your risk of serious side effects may be increased.

**What are the possible side effects of oxymorphone hydrochloride extended-release tablets?**

Some possible side effects of oxymorphone hydrochloride extended-release tablets include:

- Abnormal thinking or behavior changes.
- daytime drowsiness.
- Difficulty sleeping.
- Feeling of depression.
- Feeling of being relaxed.
- Heart attack (thickened heart muscle) is common with oxymorphone hydrochloride extended-release tablets, which can occur in a short time or may not be noticed until long after you stop taking it. Call your doctor right away if you have chest pain or discomfort, or pain in your jaw, neck, or shoulder.

**How should I take oxymorphone hydrochloride extended-release tablets?**

- Follow all directions as your doctor has prescribed.
- Take oxymorphone hydrochloride extended-release tablets exactly as prescribed by your doctor. Do not change your dose or stop taking oxymorphone hydrochloride extended-release tablets without talking to your doctor.

**What should I avoid while taking oxymorphone hydrochloride extended-release tablets?**

- Avoid taking oxymorphone hydrochloride extended-release tablets if you plan to drive, operate heavy machinery, or do any other activities that require alertness, as oxymorphone hydrochloride extended-release tablets may make you drowsy.

**How should I store oxymorphone hydrochloride extended-release tablets?**

- Store oxymorphone hydrochloride extended-release tablets at room temperature, 59°F to 86°F (15°C to 30°C). Keep oxymorphone hydrochloride extended-release tablets out of the reach of children.

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- Avoid taking oxymorphone hydrochloride extended-release tablets if you plan to drive, operate heavy machinery, or do any other activities that require alertness, as oxymorphone hydrochloride extended-release tablets may make you drowsy.

**How should I store oxymorphone hydrochloride extended-release tablets?**

- Store oxymorphone hydrochloride extended-release tablets at room temperature, 59°F to 86°F (15°C to 30°C). Keep oxymorphone hydrochloride extended-release tablets out of the reach of children.
The possible side effects of oxymorphone hydrochloride extended-release tablets:  
- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain.  
Call your healthcare provider if you have any of these symptoms and they are severe.  
So emergency medical help if you have:  
- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme dizziness, tight-headedness when changing positions, or you are feeling faint.  
These are not all the possible side effects of oxymorphone hydrochloride extended-release tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov. For more information about oxymorphone hydrochloride extended-release tablets, call Actavis toll-free at 1-866-423-0834.

This Medication Guide has been approved by the U.S. Food and Drug Administration. 

Manufactured by:  
Actavis Elizabeth LLC  
200 Elmore Avenue  
Elizabeth, NJ 07207 USA  
40-0236 (MG 41-1184/014)  
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8. DRUG INTERACTIONS  
8.1 General Information  

The use of oxymorphone hydrochloride extended-release tablets may increase the risk of serious cardiovascular adverse reactions, such as MI or stroke, in patients taking certain other medicines. These adverse events have been observed primarily in studies involving patients with severe chronic pain who were taking concomitant medications to treat other medical conditions. Oxymorphone hydrochloride extended-release tablets should be used with caution in patients already receiving a vasoconstrictor or other medicine for the treatment of these conditions. These medicines include:  
- Antihypertensives (e.g., methyldopa, reserpine, guanethidine, clonidine, prazosin, metoprolol, atenolol, labetalol, minoxidil)  
- Beta-blockers (e.g., propranolol, metoprolol, atenolol)  
- Calcium channel blockers (e.g., nifedipine, diltiazem, verapamil)  
- Sympathomimetics (e.g., amphetamines, ephedrine, pseudoephedrine)  
- Other medicines for the treatment of hypertension, such as diuretics  
- Other medicines for the treatment of angina, such as nitroglycerin, isosorbide dinitrate, bosentan, or bosentan and astatide  
- Other medicines for the treatment of asthma, such as theophylline or albuterol  
- Antipsychotics (e.g., clozapine, olanzapine, quetiapine, risperidone, ziprasidone)  
- Other medicines for the treatment of seizure disorders, such as carbamazepine, lamotrigine, phenytoin, topiramate, valproic acid  
- Orlistat  

8.2 Specific Drug Interactions  

When oxymorphone hydrochloride extended-release tablets are used in combination with medicines that cause drowsiness or sedation, such as antihistamines, tranquilizers, opiate analgesics, alcohol, or other medicines for the treatment of sleep disorders, the risk of drowsiness and oversedation may increase.  

9. PATIENT FOCUS  

9.1 Patient Information  

Patients should be counseled to take oxymorphone hydrochloride extended-release tablets as prescribed by their healthcare provider. Patients should be advised to discuss any concerns about oxymorphone hydrochloride extended-release tablets with their healthcare provider.  

9.1.1 Safety Information  

Patients should be advised to take oxymorphone hydrochloride extended-release tablets exactly as prescribed by their healthcare provider. Patients should be advised to take oxymorphone hydrochloride extended-release tablets with food to reduce nausea.  

9.1.2 Storage Information  

Patients should be advised not to crush or chew oxymorphone hydrochloride extended-release tablets. Patients should be advised that oxymorphone hydrochloride extended-release tablets are not for injection.  

9.1.3 Disposal Information  

Patients should be advised to discard unused oxymorphone hydrochloride extended-release tablets by flushing them down the toilet.  

10. OVERDOSAGE  

Overdose  

10.1 General Information  

10.1.1 Clinical Management  

The management of an oxymorphone hydrochloride extended-release tablets overdose should be symptomatic and supportive. Cardiac and pulmonary monitoring should be implemented. Treatment with activated charcoal may be considered if used soon after ingestion. Other treatment may include treatments for respiratory depression, including administering naloxone if available.  

10.1.2 Treatment in the Clinical Laboratory  

Specific treatment in the clinical laboratory is not considered necessary.  

10.2 Symptoms of Overdose  

Symptoms of oxymorphone hydrochloride extended-release tablets overdose may include:  
- Nausea  
- Vomiting  
- Decreased level of consciousness  
- Difficulty breathing  
- Convulsions  

10.3 Treatment of Overdose  

10.3.1 Gastric Lavage  

Gastric lavage is not recommended as it may result in aspiration pneumonia.  

10.3.2 Naloxone  

Naloxone, a specific opiate antagonist, is available as a parenteral and subcutaneous injectable formulation. Naloxone is not recommended to completely reverse the effects of oxymorphone hydrochloride extended-release tablets. Other supportive measures should be administered as medically indicated.  

11. HOW TO GET MORE INFORMATION  

For more information, contact the Actavis toll-free number at 1-866-423-0834.  

12. REFERENCES  

12.1 Literature Cited  

This information is for your use only and is not intended to be a complete and comprehensive summary of the information contained in this Medication Guide. This Medication Guide should be used in conjunction with the directions for use on the label of oxymorphone hydrochloride extended-release tablets. This Medication Guide may not include all possible side effects. Other medicine, laboratory tests, and medical advice may also apply to oxymorphone hydrochloride extended-release tablets. This Medication Guide is not intended to replace the information contained on the label of the product. For answers to additional questions, contact Actavis toll-free at 1-866-423-0834.
Oxymorphone hydrochloride extended-release tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not for use to treat pain that is not around-the-clock.

Important information about oxymorphone hydrochloride extended-release tablets:

- Get emergency help right away if you take too much oxymorphone hydrochloride extended-release tablets (overdose). When you first start taking oxymorphone hydrochloride extended-release tablets, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Never give anyone your oxymorphone hydrochloride extended-release tablets. They could die from taking it. Store oxymorphone hydrochloride extended-release tablets away from children and in a safe place to prevent stealing or abuse. Selling or giving away oxymorphone hydrochloride extended-release tablets is against the law.

Do not take oxymorphone hydrochloride extended-release tablets if you have:

- Severe asthma, trouble breathing, or other lung problems.
- A bowel blockage or have narrowing of the stomach or intestines.

Before taking oxymorphone hydrochloride extended-release tablets, tell your healthcare provider if you have a history of:

- Head injury, seizures
- Liver, kidney, thyroid problems
- Problems urinating
- Pancreas or gallbladder problems
- Abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- Pregnant or planning to become pregnant. Prolonged use of oxymorphone hydrochloride extended-release tablets during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- Breastfeeding. Oxymorphone hydrochloride extended-release passes into breast milk and may harm your baby.
- Taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking oxymorphone hydrochloride extended-release tablets with certain other medicines can cause serious side effects.
When taking oxymorphone hydrochloride extended-release tablets:

• Do not change your dose. Take oxymorphone hydrochloride extended-release tablets exactly as prescribed by your health-care provider.
• Take your prescribed dose every 12 hours at the same time every day on an empty stomach, at least 1 hour before or 2 hours after meals. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take your next dose at your usual time.
• Swallow oxymorphone hydrochloride extended-release tablets whole. Do not cut, break, chew, crush, dissolve, snort, or inject oxymorphone hydrochloride extended-release tablets because this may cause you to overdose and die.
• Call your healthcare provider if the dose you are taking does not control your pain.
• Do not stop taking oxymorphone hydrochloride extended-release tablets without talking to your healthcare provider.
• After you stop taking oxymorphone hydrochloride extended-release tablets, flush any unused tablets down the toilet.

While taking oxymorphone hydrochloride extended-release tablets DO NOT:

• Drive or operate heavy machinery, until you know how oxymorphone hydrochloride extended-release tablets affect you. Oxymorphone hydrochloride extended-release tablets can make you sleepy, dizzy, or lightheaded.
• Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with oxymorphone hydrochloride extended-release tablets may cause you to overdose and die.

The possible side effects of oxymorphone hydrochloride extended-release tablets:

• constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.
• Get emergency medical help if you have:
• trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, light-headedness when changing positions, or you are feeling faint.

These are not all the possible side effects of oxymorphone hydrochloride extended-release tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov. For more information about oxymorphone hydrochloride extended-release tablets, call Actavis at 1-800-432-8534.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:
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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST
04/16/2014
Deputy Director, Office of Generic Drugs, for Kathleen Uhl, M.D.