**OXYCODONE (ox’i koe’done) AND ACETAMINOPHEN (a set a’min oh’ fen) TABLETS**

**OXYCODONE and acetaminophen tablets are:**
- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage moderate to moderately severe pain. It can be habit forming and is a controlled substance.

**WARNINGS**

- **Life-Threatening Opioid-Induced Respiratory Depression:**
  - Opioids may cause or worsen respiratory depression, a life-threatening condition that makes you feel like you’re not getting enough air. It may be life-threatening if not recognized and treated.
  - If you have lung or heart disease, long-term treatment with opioids may be more harmful to you. 
  - Do not take this medicine if you have a history of lung disease (such as chronic obstructive pulmonary disease or asthma), heart disease, or if you have a history of severe respiratory depression.

- **Overdose and Death:**
  - Taking too many or taking this medicine for a long time can cause serious or life-threatening breathing problems. Taking too many (overdose) or taking for too long can cause a condition called physical dependence, where you must take the medicine to avoid withdrawal symptoms. Do not discontinue the medicine suddenly without talking to your healthcare provider.

- **Do not take oxycodone and acetaminophen tablets if you have:**
  - Severe asthma, trouble breathing, or other lung problems.
  - A blood clot or have narrowing of the stomach or intestines.
  - Known hypersensitivity to oxycodone, acetaminophen, or any other component of this product.
  - Pregnancy.

- **Important Information about oxycodone and acetaminophen tablets:**
  - Get emergency help right away if you take too many oxycodone and acetaminophen tablets (overdose).
  - When you first start taking oxycodone and acetaminophen tablets, when your dose is changed, or if you take too many (overdose), serious or life-threatening breathing problems that can lead to death may occur.

- **Taking oxycodone and acetaminophen tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs such as “speed,” “heroin,” “PCP,” “speed,” “heroin,” “PCP,” or “kief”) may increase the risk of serious or life-threatening breathing problems that can lead to death.**

**CONTRAINDICATIONS**

- **Do not take oxycodone and acetaminophen tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs such as “speed,” “heroin,” “PCP,” “speed,” “heroin,” “PCP,” or “kief”).**

**WARNINGS**

- **Habit Formation, Abuse, and Dependence:**
  - Opioids may cause or worsen addiction, abuse, and dependence. People with a history of drug abuse, especially those with a history of opioid abuse, may be at a higher risk for misuse and abuse.
  - Do not share oxycodone and acetaminophen tablets with others. This medicine may harm others and cause serious or life-threatening respiratory depression or death.

**Important Information about oxycodone and acetaminophen tablets:**

- **Stop taking oxycodone and acetaminophen tablets if you have:**
  - Severe asthma, trouble breathing, or other lung problems.
  - A blood clot or have narrowing of the stomach or intestines.
  - Known hypersensitivity to oxycodone, acetaminophen, or any other component of this product.

**Important Information about oxycodone and acetaminophen tablets:**

- **Before taking oxycodone and acetaminophen tablets, tell your healthcare provider if you have:**
  - Head injury, seizures, liver or kidney problems, respiratory problems, or if you are pregnant.
  - Napping, sedation, or trouble sleeping.
  - Liver or kidney problems.
  - Allergic reactions to other medicines or products containing FD&C Yellow No. 5 (tartrazine) or other ingredients.

**Prevent Abuse and Deterrence of Oxycodone and Acetaminophen Tablets**

- **Do not take oxycodone and acetaminophen tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants. (See CLINICAL PHARMACOLOGY, WARNINGS, PRECAUTIONS; BOXED WARNING).**

**Prevent Abuse and Deterrence of Oxycodone and Acetaminophen Tablets**

- **Before taking oxycodone and acetaminophen tablets, tell your healthcare provider if you have:**
  - A history of substance abuse, especially alcohol or opioid abuse.
  - A history of mental health disorders.

**Prevent Abuse and Deterrence of Oxycodone and Acetaminophen Tablets**

- **Tell your healthcare provider if you are:**
  - Pregnant or planning to become pregnant.
  - Breastfeeding.
  - Taking other medicines such as benzodiazepines, antidepressants, or other central nervous system depressants.

**Prevent Abuse and Deterrence of Oxycodone and Acetaminophen Tablets**

- **Before taking oxycodone and acetaminophen tablets, tell your healthcare provider if you are:**
  - Taking benzodiazepines or other CNS depressants including alcohol or other sedative or hypnotic drugs.
  - Taking other medicines that can cause serious or life-threatening respiratory depression or death.

**Prevent Abuse and Deterrence of Oxycodone and Acetaminophen Tablets**

- **Tell your healthcare provider if you are:**
  - Taking benzodiazepines or other CNS depressants including alcohol or other sedative or hypnotic drugs.
  - Taking other medicines that can cause serious or life-threatening respiratory depression or death.

**Important Information about oxycodone and acetaminophen tablets:**

- **Before taking oxycodone and acetaminophen tablets, tell your healthcare provider if you have:**
  - Head injury, seizures, liver or kidney problems, respiratory problems, or if you are pregnant.
  - Recent, recurrent, or uncontrolledited.

**Important Information about oxycodone and acetaminophen tablets:**

- **Before taking oxycodone and acetaminophen tablets, tell your healthcare provider if you have:**
  - Head injury, seizures, liver or kidney problems, respiratory problems, or if you are pregnant.
  - Napping, sedation, or trouble sleeping.
  - Liver or kidney problems.
  - Allergic reactions to other medicines or products containing FD&C Yellow No. 5 (tartrazine) or other ingredients.

**Important Information about oxycodone and acetaminophen tablets:**

- **Before taking oxycodone and acetaminophen tablets, tell your healthcare provider if you have:**
  - A history of substance abuse, especially alcohol or opioid abuse.
  - A history of mental health disorders.

**Important Information about oxycodone and acetaminophen tablets:**

- **Tell your healthcare provider if you are:**
  - Pregnant or planning to become pregnant.
  - Breastfeeding.
  - Taking other medicines such as benzodiazepines, antidepressants, or other central nervous system depressants.

**Important Information about oxycodone and acetaminophen tablets:**

- **Before taking oxycodone and acetaminophen tablets, tell your healthcare provider if you have:**
  - A history of substance abuse, especially alcohol or opioid abuse.
  - A history of mental health disorders.

**Important Information about oxycodone and acetaminophen tablets:**

- **Tell your healthcare provider if you are:**
  - Taking benzodiazepines or other CNS depressants including alcohol or other sedative or hypnotic drugs.
  - Taking other medicines that can cause serious or life-threatening respiratory depression or death.

**Important Information about oxycodone and acetaminophen tablets:**

- **Before taking oxycodone and acetaminophen tablets, tell your healthcare provider if you have:**
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**Important Information about oxycodone and acetaminophen tablets:**

- **Tell your healthcare provider if you are:**
  - Taking benzodiazepines or other CNS depressants including alcohol or other sedative or hypnotic drugs.
  - Taking other medicines that can cause serious or life-threatening respiratory depression or death.
The possible side effects of oxycodone and acetaminophen tablets:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, diziness, 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, tightness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme dizziness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes.

These are not all the possible side effects of oxycodone and acetaminophen 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

Manufactured for: Qualitix Pharmaceuticals
Huntington, WV, 25701 call 1-800-444-4011

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

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