**HYDROCODONE BITARTRATE** (f'g’ doe kon’ bee tar tar’ trik) AND ACETAMINOPHEN (p’oos’ en’ o fen) TABLETS USP

**Tablets**  
- Hydrocodone bitartrate  
- Acetaminophen  
- This product contains both hydrocodone and acetaminophen. Each tablet contains:
  - Hydrocodone bitartrate 7.5 mg
  - Acetaminophen 325 mg

**Indications**  
- Oral tablets are indicated for the management of moderate to moderately severe pain.

**Contraindications**  
- Hypersensitivity to hydrocodone, acetaminophen, or any component of the tablets.
- Patients with a history of idiopathic or spontaneous hepatic failure.

**Warnings**  
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment.
- Severe hepatic disease.

**Precautions**  
- Elderly, cachectic, or debilitated patients:  
  - Elderly patients may be more susceptible to the respiratory depressant effects of opioids.

**Drug Interactions**  
- Hydrocodone and acetaminophen are metabolized by the hepatic cytochrome P450 (CYP) 3A4 enzyme system.  
- Concurrent administration of hydrocodone and acetaminophen with known CYP 3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, ritonavir, and azole antifungal agents) may increase the plasma concentration of hydrocodone and acetaminophen.

**Adverse Reactions**  
- Central nervous system:  
  - Sedation, dizziness.

**Overdose**  
- Symptoms:  
  - Severe respiratory depression, coma, convulsions.

**Pharmacology**  
- Hydrocodone bitartrate is an opioid analgesic and antitussive and occurs as fine, white crystals. It is a Schedule II controlled substance.  
- Acetaminophen is a nonsteroidal anti-inflammatory drug (NSAID) that inhibits prostaglandin synthetase.  
- The analgesic action of acetaminophen involves peripheral influences, but the specific mechanism is not known.

**Dosage and Administration**  
- Initially, it is recommended to use the lowest effective dose of hydrocodone bitartrate and acetaminophen tablets.  
- Increase the dose in small increments based on the patient's response and tolerance.

**Pregnancy**  
- Hydrocodone and acetaminophen are excreted in breast milk.  
- Breastfeeding is not recommended during therapy.

**Nursing Women**  
- Breastfeeding is not recommended during therapy.

**Pediatrics**  
- Safety and effectiveness in children under 12 years of age have not been established.

**Geriatric Use**  
- Elderly patients are generally more sensitive to the effects of opioids.

**Other Warnings and Precautions**  
- Inform patients of the risk of addiction, abuse, and misuse of hydrocodone bitartrate and acetaminophen tablets.

**Revised: 04/2012**
When taking hydrocodone bitartrate and acetaminophen tablets:

- Do not change your dose. Take hydrocodone bitartrate and acetaminophen tablets exactly as prescribed by your healthcare provider.
- Take your prescribed dose every four to six hours at the same time every day. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking hydrocodone bitartrate and acetaminophen tablets regularly, do not stop taking hydrocodone bitartrate and acetaminophen tablets without talking to your healthcare provider.
- After you stop taking hydrocodone bitartrate and acetaminophen tablets, the unused tablets should be disposed of by flushing down the toilet.

When taking hydrocodone bitartrate and acetaminophen tablets (cont.)

- Drive or operate heavy machinery, until you have taken hydrocodone bitartrate and acetaminophen tablets and you know how the tablets affect you. Hydrocodone bitartrate and acetaminophen tablets can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medications that contain alcohol. Taking hydrocodone bitartrate and acetaminophen tablets with alcohol or alcohol-containing medications may cause you to overmedicate and become drowsy.
- The possible side effects of hydrocodone bitartrate and acetaminophen 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, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of hydrocodone bitartrate 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 by:
QUALITY PHARMACEUTICALS, Huntsville, AL 35811
1-800-446-4001

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

Issued: 04/2016
RD 01/01/2016

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Acetaminophen tablets:

- Do not change your dose. Take acetaminophen tablets exactly as prescribed by your healthcare provider.
- Take your prescribed dose every four to six hours at the same time every day. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking acetaminophen tablets regularly, do not stop taking acetaminophen tablets without talking to your healthcare provider.
- After you stop taking acetaminophen tablets, the unused tablets should be disposed of by flushing down the toilet.

When taking acetaminophen tablets:

- Do not take any other medications containing acetaminophen tablets without talking to your healthcare provider.
- Do not take acetaminophen tablets if you are allergic to any ingredient in acetaminophen tablets.
- Do not take acetaminophen tablets when the patient is a child.

The possible side effects of acetaminophen 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, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

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