Hydrocodone Bitartrate and Acetaminophen Oral Solution

(7.5 mg / 325 mg per 15 mL)

Usual Dosage: See package insert for complete dosage recommendations.

Pharmacist: Dispense in a tight, light-resistant container with a child-resistant closure. Dispense the Patient Information Leaflet with the drug product.

Storage: Store at 20° - 25°C (68°-77°F). [See USP Controlled Room Temperature].

WARNING: Keep this and all medications out of the reach of children. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured for:
Boca Pharmacal, LLC
a Subsidiary of Qualitest Pharmaceuticals
Huntsville, AL 35811
Rev. 08/14 400574-16
**Dosage and Administration**

Dosage should be adjusted according to severity of the pain and the response of the patient. However, it should be kept in mind that tolerance to hydrocodone can develop with continued use and that the incidence of untoward effects is dose related.

**Storage**

- Keep out of reach of children.
- Store at room temperature (protect from heat and light).

**Signs and Symptoms**

Hydrocodone: Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, respiratory arrest, circulatory collapse, and death.

**Missed Dose**

It is important that you do not take more than a single dosage at one time, or that you don't take doses at intervals less than 4 hours apart.

**Gastric Decontamination**

Gastric decontamination with activated charcoal should be administered just prior to N-acetylcysteine (NAC) to decrease absorption if acetaminophen is known or suspected to have been ingested. NAC is indicated in acetaminophen poisoning when there are risk factors for hepatotoxicity, such as ingestion of more than the recommended dosage or a history of alcohol abuse, or when there is evidence of evolving liver injury. Intravenous NAC may be administered when circumstances preclude oral administration.

**WARNINGS**

- Do not double the prescribed dose.
- Do not exceed the recommended dosage.
- Do not take this medication if you are allergic to hydrocodone or acetaminophen.
- Do not take this medication if you are pregnant or breast-feeding.
- Do not take this medication if you have a history of drug or alcohol abuse.
- Do not take this medication if you have emphysema, asthma, or other chronic lung disease.
- Do not take this medication if you have liver disease.
- Do not take this medication if you have kidney disease.
- Do not take this medication if you have underactive thyroid or Addison's disease.
- Do not take this medication if you have an enlarged prostate or difficulty urinating.
- Do not take this medication if you are taking other medications that can cause liver damage.
- Do not take this medication if you are taking other medications that can cause increased bleeding.

**USES**

Hydrocodone bitartrate and acetaminophen oral solution is used to relieve moderate to moderately severe pain. You should not exceed the recommended dosages for pain relief.

**ADVERSE REACTIONS**

- The most common adverse reactions are dizziness, drowsiness, nausea, vomiting, and constipation.
- Other possible adverse reactions include allergic reactions, skin reactions, and hepatic injury.

**PRECAUTIONS**

- Use caution when driving or operating machinery.
- Avoid alcohol and other medications that can cause drowsiness.
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**INTERACTIONS**

- Do not take this medication with other medications that can cause drowsiness.
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**DOSE AND ADMINISTRATION**

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**STORAGE**

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- Store at room temperature (protect from heat and light).

**SIDE EFFECTS**

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Hydrocodone bitartrate and acetaminophen is supplied in liquid form for oral administration. Drug Interactions

WARNING: May be habit-forming. Acetaminophen may produce false-positive test results for urinary 5-hydroxyindoleactic acid.

No adequate studies have been conducted in animals to determine whether hydrocodone has a potential for carcinogenesis, mutagenesis, or impairment of fertility. Hydrocodone has not demonstrated mutagenic potential. Acetaminophen has not demonstrated mutagenic potential. Teratogenic Effects

In addition, the liquid contains the following inactive ingredients: citric acid anhydrous, ethyl maltol, glycerin, propylene glycol, sodium benzoate, sorbic acid, water, and the following colors: FD&C Red #33 and FD&C Red #40 as coloring and natural and artificial flavoring.

Cough Reflex

Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when hydrocodone bitartrate and acetaminophen oral solution is used postoperatively and in patients with pulmonary disease.

Hydrocodone, like all narcotics, may impair mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. Such tasks should be avoided while taking this product.