INDICATIONS AND USAGE
Hydrocodone bitartrate and acetaminophen oral solution is indicated for the relief of moderate to moderately severe pain.

CONTRAINDICATIONS
This product should not be administered to those who have previously exhibited sensitivity to hydrocodone, acetaminophen, or any other component of this product. Patients known to be hypersensitive to other opioids may exhibit cross-sensitivity to the ingredients. Drug Dependence

WARNINGS
Hydrocodone has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases were in individuals who ingested more than 4,000 milligrams per day of acetaminophen. Most cases of acute liver failure, at times resulting in liver transplant and death, occurred in patients who ingested acetaminophen at doses that exceed 4,000 milligrams per day, and often in combination with one or more other acetaminophen-containing products. The possibility of acetaminophen hepatotoxicity in such cases should be considered if symptoms of liver injury occur during treatment with hydrocodone bitartrate and acetaminophen oral solution. Early symptoms of liver injury may occur with the first few days of use and may be accompanied by jaundice and/or other clinical indications of liver dysfunction. If signs and symptoms suggestive of liver injury occur during treatment, patients should be advised to discontinue the drug immediately and seek medical attention.

Hydrocodone and acetaminophen oral solution contains:

Chemical Name: Hydrocodone bitartrate and acetaminophen (hydrate). Hydrocodone bitartrate and acetaminophen oral solution is for oral use.

Hepatotoxicity

OVERDOSAGE
Hydrocodone suppresses the cough reflex, as indicated for use when hydrocodone bitartrate and acetaminophen oral solution is used postoperatively and in patients with pulmonary disease. Information for Patients/Carers

• Do not take hydrocodone bitartrate and acetaminophen oral solution if you are allergic to any of its ingredients.

If you develop signs of allergy such as a rash and take hydrocodone bitartrate and acetaminophen oral solution, seek your healthcare provider’s advice immediately.

• Do not take more than 4,000 milligrams of acetaminophen per day. Call your doctor if you feel you have taken too much acetaminophen.

Hydrocodone, like all narcotics, may impair the ability to perform potentially hazardous tasks or drive a car or operate machinery. Such tasks should be avoided while taking this medication.

Hydrocodone bitartrate and acetaminophen oral solution can cause nausea, dizziness, lightheadedness, nausea, shortness of breath, unusual tiredness, and vomiting. Take this medicine as directed by your doctor. Do not take more of it, do not take more often, and do not take for a longer time than your doctor ordered.

Uses

Hydrocodone bitartrate and acetaminophen oral solution is an analgesic used to relieve moderate to moderately severe pain. Hydrocodone bitartrate and acetaminophen oral solution is a combination product containing hydrocodone (hydri-de-KO-done) bitartrate and acetaminophen (a-seat-a-MIN-oh-len). Hydrocodone is a narcotic pain reliever and acetaminophen is an antipyretic. It has the following structural formula:

\[
\text{Hydrocodone: \(\text{C}_{27}\text{H}_{41}\text{NO}_4\text{O}_5\)}
\]

\[
\text{Acetaminophen: \(\text{C}_{7}\text{H}_{10}\text{NO}_2\)}
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It is very important that hydrocodone bitartrate and acetaminophen oral solution be dosed accurately. A household teaspoon or tablespoon is not an adequate measuring device, especially when one-half or three-fourths of a teaspoonful is to be measured accurately.

Since a household teaspoon is not accurate and can be mixed-up with a tablespoon (which can cause overdosage), it is strongly recommended that you obtain and use a specially calibrated measuring device. Ask your doctor or pharmacist for help to find a dropper that can measure the needed dose properly and ask for help if you do not understand how to use the dropper.

### Missed Dose

- **To avoid a possible overdose, it is important that you do not take more than a single dosage at one time**, that you do not take dosages at intervals less than 4 hours apart.
- **If you miss taking a dose of hydrocodone bitartrate and acetaminophen oral solution, take it as soon as you remember. However, make sure to wait at least 4 hours before taking your next dose.**
- **If you missed taking a dose and it is almost time for your next dose, skip the missed dose and take your medicine as scheduled.**
- **Do not double the prescribed dose.**

### Possible Side Effects

Side effects you may experience include abdominal pain, constipation, difficulty urinating, dizziness and drowsiness, fear, fuzzy thinking, general feeling of discomfort or illness, lightheadedness, mood changes, nausea, nervousness, rash, shortness of breath, slower reactions, unusual tiredness, and vomiting. **Call your doctor if these effects continue or are bothersome.** Side effects not listed above may sometimes occur. If you notice any other effects, check with your doctor.

### Storage

- **Keep out of reach of children.**
- **Store at room temperature (protect from heat, do not refrigerate).**
- **Keep in original labeled bottle.**
- **Discard medicines that are old or no longer needed.**
- **Even a single overdose of this medicine may be a life-threatening situation. If you suspect that you or someone else may have taken more than the prescribed dose of this medicine, contact your local poison control center and ask for the nearest emergency room.**

### Drug Interactions

- **This leaflet provides a summary of information about hydrocodone bitartrate and acetaminophen oral solution. If you have any questions or concerns, or want more information, talk to your doctor or pharmacist.**

### Dosage and Administration

- **The total daily dosage for children should not exceed 6 doses per day.**
- **It is of utmost importance that the dose of hydrocodone bitartrate and acetaminophen oral solution be administered accurately.**

### Hydrocodone Bitartrate and Acetaminophen Oral Solution (75 mg/325 mg per 5 mL)

- **WARNING: may be habit-forming; this drug contains 15 mg hydrocodone bitartrate (7.5 mg/5 mL) and 7% alcohol. It is supplied in a container of 16 oz (473 mL) NDC 64376-640-16 and 4 oz (118 mL) NDC 64376-640-40.**

### HOW SUPPLIED

- **Hydrocodone Bitartrate and Acetaminophen Oral Solution (75 mg/325 mg per 5 mL) is a red-colored, tropical fruit-flavored flavored liquid containing hydrocodone bitartrate (7.5 mg/5 mL), U.S.P., and acetaminophen (325 mg/5 mL), U.S.P., in a base of water for injection, USP.**

### Table on the next page

- **The table on the next page, and are to be given every 4 to 6 hours as needed for pain.**
- **The usual adult dosage is one tablespoonful every 4 to 6 hours as needed for pain.**
- **The usual daily dosage for adults should not exceed 6 tablespoonfuls (30 mL) per day.**
- **The usual dosages for children are given by the table on the next page, and are to be given every 4 to 6 hours as needed for pain.**

### Table

- **For healthy professionals that you can ask to read.**
- **Call your doctor for medical advice about side effects.**
- **Update side effects to FDA at 1-800-FDA-1088.**

### Manufactured for:

- **Boca Pharmacal, LLC a Subsidiary of Qualitests Pharmaceuticals**

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### Rev. 2

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