

Patient Information Leaflet
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
ORAL SOLUTION
7.5 mg/500 mg per 15 mL



Rx only

Summary

Hydrocodone bitartrate and acetaminophen oral solution is used to relieve moderate to moderately severe pain. You should not take hydrocodone bitartrate and acetaminophen oral solution if you are allergic to hydrocodone or acetaminophen. The most common side effects of hydrocodone bitartrate and acetaminophen oral solution are abdominal pain, dizziness, drowsiness, light-headedness, 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 it more often, and do not take it 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 (hye-droe-KO-done) bitartrate and acetaminophen (a-seat-a-MIN-oh-fen). Hydrocodone is a narcotic pain reliever and a cough suppressant. Acetaminophen is a non-narcotic pain reliever and fever reducer. A narcotic analgesic and acetaminophen used together may provide better pain relief than either product used alone. If you have any questions, please call your doctor or pharmacist.

General Cautions

- Do not take this drug if you have allergies or unusual reactions to narcotic pain relievers or acetaminophen because it is likely that you may also be allergic to hydrocodone bitartrate and acetaminophen oral solution.
- This product may inhibit your mental and physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. Such tasks should be avoided while you are taking this product.
- This medicine may not be right for you. Check with your doctor or pharmacist, if you:
 - are pregnant.
 - are nursing.
 - are taking other medications: narcotic pain relievers; allergy medicines; anti-depressant medicines; acetaminophen-containing medicines or other medicines that cause central nervous system depression, including alcohol.
 - have other medical problems: a history of drug or alcohol abuse; recent head injury; emphysema, asthma, or other chronic lung disease; liver disease, kidney disease; underactive thyroid, Addison's disease, enlarged prostate or difficulty urinating.

Proper Use

Take this medicine as directed by your doctor. Do not share it with anyone else. This medicine can cause drug dependence and has the potential for abuse. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. If you think that this medicine is not working properly after taking it for some time, do not increase the dose. Check with your doctor or pharmacist.

Dosing

The dose of this medication will be different for different patients. Follow the directions provided by your doctor. The following information includes only the average doses of this medication. *If your dose is different, do not change doses unless your doctor tells you to do so.*

BODY WEIGHT	APPROXIMATE AGE	DOSE every 4 to 6 hours	MAXIMUM TOTAL DAILY DOSE (6 doses per day)
12 to 15 kg 27 to 34 lbs.	2 to 3 years	$\frac{3}{4}$ teaspoonful = 3.75 mL	$4\frac{1}{2}$ teaspoonfuls = 22.5 mL
16 to 22 kg 35 to 50 lbs.	4 to 6 years	1 teaspoonful = 5 mL	6 teaspoonfuls = 30 mL
23 to 31 kg 51 to 69 lbs.	7 to 9 years	$1\frac{1}{2}$ teaspoonfuls = 7.5 mL	9 teaspoonfuls = 45 mL
32 to 45 kg 70 to 100 lbs.	10 to 13 years	2 teaspoonfuls = 10 mL	12 teaspoonfuls = 60 mL
46 kg and up 101 lbs. and up	14 years to adult	1 Tablespoonful = 15 mL	6 Tablespoonfuls = 90 mL

It is very important that hydrocodone bitartrate and acetaminophen oral solution be dosed accurately. A household teaspoon or tablespoon is not an accurate measuring device, especially when one-half or three-fourths of a teaspoonful is to be measured.

Since a household teaspoon is not accurate and can be mixed-up with a tablespoon (which can cause overdose), it is strongly recommended that you obtain and use a proper 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, or that you don't take doses 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, drowsiness, fear, fuzzy thinking, general feeling of discomfort or illness, light-headedness, 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 or emergency room immediately. This medicine was prescribed for your particular condition. Do not use it for another condition or give the drug to others.
- This leaflet summarizes the most important information about hydrocodone bitartrate and acetaminophen oral solution. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about hydrocodone bitartrate and acetaminophen oral solution that was written for healthcare professionals, or you can visit www.Mallinckrodt.com or call 1-800-778-7898.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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