

Palmetto State Pharmaceuticals

Patient Drug Education

HYDROCODONE/APAP 5/500 TAB

USES:

This medication is a combination of a narcotic (hydrocodone) and a non-narcotic (acetaminophen) used to relieve moderate to severe pain. Hydrocodone works by binding to opioid receptors in the brain and spinal cord, and acetaminophen decreases the formation of prostaglandins, therefore relieving pain.

HOW TO TAKE THIS MEDICATION:

HOW TO USE: Take this medication by mouth, as directed by your doctor. You may take this drug with or without food. If you have nausea, you may take this drug with food, although doing so may decrease its effectiveness. Consult your doctor or pharmacist about alternatives for decreasing nausea (e.g., antihistamines, lying down for 1-2 hours with minimal head movement). If you are using the liquid product, measure the medication with a dose-measuring spoon or device to make sure you get the correct dose. Do not use a household spoon. The dosage is based on your medical condition and response to therapy. Pain medications work best in relieving pain before it becomes severe. Once the pain becomes intense, the medication is not as effective in relieving it. Use this medication exactly as prescribed. Do not increase your dose, take it more frequently or use it for a longer period of time than prescribed because this drug can be habit-forming. Also, if used for an extended period of time, do not suddenly stop using this drug without your doctor's approval. When used for an extended period, this medication may not work as well and may require different dosing. Talk with your doctor if this medication stops working well. This medication contains acetaminophen. Do not take more acetaminophen than recommended (see Side Effects section). Inform your doctor if your condition persists or worsens.

SIDE EFFECTS:

Nausea, vomiting, constipation, lightheadedness, dizziness, drowsiness, flushing, vision changes, or mental/mood changes may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: slow/irregular breathing, slow/irregular heartbeat, change in the amount of urine. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: impairment or loss of hearing (especially with high doses for long periods). If you do not have liver problems, the adult maximum dose of acetaminophen is 4 grams per day (4000 milligrams). If you take more than the maximum daily amount, it may cause serious (possibly fatal) liver disease. Tell your doctor immediately if you have any of the following symptoms of liver damage: severe nausea, yellowing eyes or skin, dark urine, stomach pain, extreme fatigue. An allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS:

Before taking this medication, tell your doctor or pharmacist if you are allergic to it; or to other narcotics (e.g. morphine, codeine); or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: severe breathing problems (e.g., respiratory depression, hypercapnia), severe diarrhea (e.g., pseudomembranous colitis, infectious diarrhea due to toxins). Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, kidney disease, difficulty urinating (e.g., enlarged prostate, urethral stricture), alcohol use, drug dependency, heart problems (e.g., slow/irregular heartbeat, very low blood pressure), abdominal/stomach problems (e.g., gallbladder disease), lung disease (e.g., asthma, chronic obstructive pulmonary disease), seizure disorders, serious head injury or brain disease, spinal problems (kyphoscoliosis), low thyroid disease (hypothyroidism), adrenal gland problems (Addison's disease), psychiatric problems (toxic psychosis). This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Avoid alcoholic beverages because they may increase the risk of side effects of this drug. This product contains acetaminophen which may cause liver damage. Daily use of alcohol, especially when combined with acetaminophen, may increase your risk for liver damage. Check with your doctor or pharmacist for more information. To minimize dizziness and lightheadedness, get up slowly when rising from a seated or lying position. Caution is advised when using this drug in the elderly because they may be more sensitive to the side effects of the drug, especially the possible decreased breathing and drowsiness effects. This medication should be used only when clearly needed during pregnancy. It is not recommended for use for long periods or in high doses near the expected delivery date because of the potential for harm to an unborn baby. Discuss the risks and benefits with your doctor. Based on information from related drugs, this drug may pass into breast milk. Due to the potential risk to the infant, consult your doctor before breast-feeding.

DRUG INTERACTIONS:

This drug should not be used with the following medications because very serious interactions may occur: naltrexone. If you are currently using any of these medications, tell your doctor or pharmacist before starting this drug. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription products you may use, especially of: other medications for pain, cimetidine, isoniazid, MAO inhibitors (e.g., furazolidone, linezolid, moclobemide, phenelzine procarbazine, selegiline, isocarboxazid, tranylcypromine), anti-seizure drugs (e.g., carbamazepine, phenobarbital, phenytoin), anticholinergic drugs/antihistamines (e.g., hydroxyzine, oxybutynin, scopolamine). Also report drugs that cause drowsiness such as: medicine for sleep (e.g., sedatives), tranquilizers, anti-anxiety drugs (e.g., diazepam), psychiatric medicines (e.g., phenothiazines such as chlorpromazine, or tricyclics such as amitriptyline), muscle relaxants, antihistamines that cause drowsiness (e.g., diphenhydramine). Acetaminophen is an ingredient in many nonprescription products and in some combination prescription medications. Read the labels carefully before taking other pain relievers, fever reducers, or

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cold products to see if they also contain acetaminophen. Consult your pharmacist if you are uncertain if your other prescription or nonprescription products contain acetaminophen. (Also see adult maximum daily dose information in Side Effects section). Do not start or stop any medicine without doctor or pharmacist approval.

NOTES:

Do not share this medication with others. It is against the law. This medication has been prescribed for your current condition only. Do not use it later for another condition unless told to do so by your doctor. A different medication may be necessary in those cases. To prevent constipation, maintain a diet adequate in fiber, drink plenty of water, and exercise. If you become constipated while using this drug, consult your pharmacist for help in selecting a laxative (e.g., stimulant-type).

MISSED DOSE:

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:

Store at room temperature between 59 and 86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.