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Acetaminophen (paracetamol) and codeine: Patient drug information

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(For additional information [see "Acetaminophen \(paracetamol\) and codeine: Drug information"](#) and [see "Acetaminophen \(paracetamol\) and codeine: Pediatric drug information"](#))

Brand Names: US

Tylenol with Codeine #3 [DSC]; Tylenol with Codeine #4 [DSC]

Brand Names: Canada

Acet Codeine 30 [DSC]; Acet Codeine 60 [DSC]; PMS-Acetaminophen/Codeine; Procet-30 [DSC]; TEVA-Emtec-30; TEVA-Lenoltec No 4; Triatec-30; Tylenol #4 [DSC]

Warning

All products:

- This drug is a strong pain drug that can put you at risk for addiction, abuse, and misuse. Misuse or abuse of this drug can lead to overdose and death. Talk with your doctor.
- This drug may cause very bad and sometimes deadly breathing problems. Call your doctor right away if you have slow, shallow, or trouble breathing.
- The chance of very bad and sometimes deadly breathing problems may be greater when you first start this drug or anytime your dose is raised.

- Even one dose of this drug may be deadly if it is taken by someone else or by accident, especially in children. If this drug is taken by someone else or by accident, get medical help right away.
- This drug has acetaminophen in it. Liver problems have happened with the use of acetaminophen. Sometimes, this has led to a liver transplant or death. Most of the time, liver problems happened in people taking more than 4,000 mg (milligrams) of acetaminophen in a day. People were also often taking more than 1 drug that had acetaminophen.
- This drug has an opioid drug in it. Severe side effects have happened when opioid drugs were used with benzodiazepines, alcohol, marijuana or other forms of cannabis, or prescription or OTC drugs that may cause drowsiness or slowed actions. This includes slow or troubled breathing and death. Benzodiazepines include drugs like alprazolam, diazepam, and lorazepam. Benzodiazepines may be used to treat many health problems like anxiety, trouble sleeping, or seizures. If you have questions, talk with the doctor.
- Many drugs interact with this drug and can raise the chance of side effects like deadly breathing problems. Talk with your doctor and pharmacist to make sure it is safe to use this drug with all of your drugs.
- Do not take with alcohol or products that have alcohol. Unsafe and sometimes deadly effects may happen.
- Get medical help right away if you feel very sleepy, very dizzy, or if you pass out. Caregivers or others need to get medical help right away if the patient does not respond, does not answer or react like normal, or will not wake up.
- Using this drug for a long time during pregnancy may lead to withdrawal in the newborn baby. This can be life-threatening. Talk with the doctor.
- Do not give to a child younger than 12 years of age. Children between 12 and 18 years of age who are very overweight or have certain other health problems like sleep apnea or other lung or breathing problems must not use this drug. If your child has been given this drug, ask the doctor for information about the benefits and risks.
- Some children have had very bad and sometimes deadly breathing problems when using codeine after surgery to remove tonsils or adenoids. Do not give to a child younger than 18 years of age who has had surgery to remove tonsils or adenoids. Talk with your child's doctor.

Liquid (solution):

- Be sure that you know how to measure your dose. Dosing errors can lead to accidental overdose and death. If you have any questions, talk with your doctor or pharmacist.

What is this drug used for?

- It is used to ease pain.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have any of these health problems: Lung or breathing problems like asthma, trouble breathing, or sleep apnea; high levels of carbon dioxide in the blood; or stomach or bowel block or narrowing.
- If you are taking any of these drugs: Buprenorphine, butorphanol, linezolid, methylene blue, nalbuphine, or pentazocine.
- If you have taken certain drugs for depression or Parkinson's disease in the last 14 days. This includes isocarboxazid, phenelzine, tranylcypromine, selegiline, or rasagiline. Very high blood pressure may happen.
- If you have been told by your doctor that you are a rapid metabolizer of some drugs.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly if you have been sitting or lying down. Be careful going up and down stairs.
- You will be watched closely to make sure you do not misuse, abuse, or become addicted to this drug.

- Long-term or regular use of opioid drugs like this drug may lead to dependence. Lowering the dose or stopping this drug all of a sudden may cause a greater risk of withdrawal or other severe problems. Talk to your doctor before you lower the dose or stop this drug. You will need to follow your doctor's instructions. Tell your doctor if you have more pain, mood changes, thoughts of suicide, or any other bad effects.
- Avoid taking other products that have acetaminophen in them. Check labels closely. Too much acetaminophen may cause liver problems.
- Follow the directions exactly. Do not take more acetaminophen in a day than directed. If you do not know how much acetaminophen you can take in a day, ask your doctor or pharmacist. Some people may take up to 4,000 mg (milligrams) in a day if told to do so by the doctor. Some people (like people with liver problems and children) should take less acetaminophen. Call your doctor right away if you have taken too much acetaminophen in a day, even if you feel well.
- If you are allergic to sulfites, talk with your doctor. Some products have sulfites.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- Long-term use of an opioid drug may lead to lower sex hormone levels. Call your doctor if you have a lowered interest in sex, fertility problems, no menstrual period (women), or change in sex ability (men).
- This drug may raise the chance of seizures in some people, including people who have had seizures in the past. Talk to your doctor to see if you have a greater chance of seizures while taking this drug.
- Taking an opioid drug like this drug may lead to a rare but very bad adrenal gland problem. Call your doctor right away if you have very bad dizziness or passing out, very bad upset stomach or throwing up, or if you feel less hungry, very tired, or very weak.
- If you are 65 or older, use this drug with care. You could have more side effects.
- The chance of very bad side effects may be higher in children. This may be more likely to happen in children who have breathing problems. Deadly breathing problems have happened with the use of codeine in some children. Talk with the doctor.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you are pregnant or you get pregnant while taking this drug, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat. Rarely, some allergic reactions have been life-threatening.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Very bad dizziness or passing out.
- Chest pain or pressure or a fast heartbeat.
- Feeling confused.
- Severe constipation or stomach pain. These may be signs of a severe bowel problem.
- Not able to pass urine or change in how much urine is passed.
- Fever, chills, or sore throat; any unexplained bruising or bleeding; or feeling very tired or weak.
- Mood changes.
- Trouble breathing, slow breathing, or shallow breathing.
- Noisy breathing.
- Breathing problems during sleep (sleep apnea).
- Change in eyesight.
- Seizures.
- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause severe health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.
- A severe and sometimes deadly problem called serotonin syndrome may happen if you take this drug with certain other drugs. Call your doctor right away if you have agitation; change in balance; confusion; hallucinations; fever; fast or abnormal heartbeat; flushing; muscle twitching or stiffness; seizures; shivering or shaking; sweating a lot; severe diarrhea, upset stomach, or throwing up; or severe headache.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Feeling dizzy, sleepy, tired, or weak.
- Constipation.
- Stomach pain.
- Upset stomach or throwing up.
- Dry mouth.
- Sweating a lot.
- Headache.
- Flushing.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- Take with or without food. Take with food if it causes an upset stomach.
- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
- Do not take this drug with other strong pain drugs or if you are using a pain patch without talking to your doctor first.
- If you have been taking this drug for a long time or at high doses, it may not work as well and you may need higher doses to get the same effect. This is known as tolerance. Call your doctor if this drug stops working well. Do not take more than ordered.

Liquid (solution):

- Measure liquid doses carefully. Use the measuring device that comes with this drug. If there is none, ask the pharmacist for a device to measure this drug.

- Do not use a household teaspoon or tablespoon to measure this drug. Doing so could lead to the dose being too high.

What do I do if I miss a dose?

- If you take this drug on a regular basis, take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- Many times this drug is taken on an as needed basis. Do not take more often than told by the doctor.

How do I store and/or throw out this drug?

- Store at room temperature protected from light. Store in a dry place. Do not store in a bathroom.
- Store this drug in a safe place where children cannot see or reach it, and where other people cannot get to it. A locked box or area may help keep this drug safe. Keep all drugs away from pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- A drug called naloxone can be used to help treat an overdose of this drug. Your doctor may order naloxone for you to keep with you while you take this drug. If you have questions about how to get or use naloxone, talk with your doctor or pharmacist. If you think there has been an overdose, get medical care right away even if naloxone has been used. Be ready to tell or show what was taken, how much, and when it happened.

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Topic 12357 Version 165.0

