PATIENT & CAREGIVER EDUCATION

Acetaminophen and Codeine

Brand Names: US
Capital/Codeine [DSC]; Tylenol with Codeine #3; Tylenol with Codeine #4

Brand Names: Canada
Procet-30

Warning

All products:

- This drug is a strong pain drug that can put your child at risk for addiction, abuse, and misuse. Misuse or abuse of this drug can lead to overdose and death. Talk with your child’s doctor.

- This drug may cause very bad and sometimes deadly breathing problems. Call the doctor right away if your child has slow, shallow, or trouble breathing.

- The chance of very bad and sometimes deadly breathing problems may be greater when your child first starts this drug or anytime the dose is raised. Talk with your child’s doctor.

- 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. Very bad and sometimes deadly liver problems like the need for a liver transplant have happened with acetaminophen use. Most of the time, liver problems have happened in people who took more acetaminophen in a day than they were told. Also, people who had liver problems were often using more than 1 drug that had acetaminophen in it. Talk with the doctor.

- This drug has an opioid drug in it. The use of opioid drugs along with a benzodiazepine drug or other drugs that may make you drowsy or slow your actions has led to very bad side effects. Side effects that have happened include slowed or trouble breathing and deaths. Benzodiazepine drugs include drugs like alprazolam, diazepam, and lorazepam. Benzodiazepine drugs are used to treat many health problems like anxiety, trouble sleeping, or seizures. Talk with the doctor.

- Many other drugs interact with this drug. These drugs can raise the chance of side effects as well as very bad and sometimes deadly breathing problems. Talk with the doctor and pharmacist to make sure that it is safe for your child to use this drug with all of his/her other drugs.

- Be sure your child does not drink alcohol or use 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.

• 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.

If your child is pregnant:

• 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.

All liquid products:

• Be sure that you know how to measure your child’s dose. Dosing errors can lead to accidental overdose and death. If you have any questions, talk with your child’s doctor or pharmacist.
What is this drug used for?

- It is used to ease pain.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child has an allergy to this drug or any part of this drug.

- If your child is allergic to any drugs like this one or any other drugs, foods, or other substances. Tell the doctor about the allergy and what signs your child had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.

- If your child has 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 your child is taking any of these drugs: Buprenorphine, butorphanol, nalbuphine, or pentazocine.

- If your child has taken certain drugs used for low mood (depression) like isocarboxazid, phenelzine, or tranylcypromine or drugs used for certain other health problems in the last 14 days. Taking this drug within 14 days of those drugs can cause very bad high blood pressure.

- If your child is taking any of these drugs: Linezolid or methylene blue.

If your child is breast-feeding a baby:
• Be sure your child does not breast-feed a baby while taking this drug.

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

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

What are some things I need to know or do while my child takes this drug?

All products:

• Tell all of your child’s health care providers that your child is taking this drug. This includes your child’s doctors, nurses, pharmacists, and dentists.

• Have your child avoid tasks or actions that call for alertness until you see how this drug affects your child. These are things like riding a bike, playing sports, or using items such as scissors, lawnmowers, electric scooters, toy cars, or motorized vehicles.

• To lower the chance of feeling dizzy or passing out, have your child rise slowly if your child has been sitting or lying down. Have your child be careful going up and down stairs.
• Allergic reactions have happened with this drug. Rarely, some reactions can be very bad or life-threatening. Talk with the doctor.

• If your child has been taking this drug for a long time or at high doses, it may not work as well and your child may need higher doses to get the same effect. This is known as tolerance. Call the doctor if this drug stops working well. Do not give more than ordered.

• If your child has been taking this drug on a regular basis and stops taking it all of a sudden, your child may have signs of withdrawal. Do not stop giving this drug all of a sudden without calling the doctor. Tell the doctor if your child has any bad effects.

• Avoid giving your child other sources of acetaminophen. Check labels closely. Too much acetaminophen may cause problems.

• Call the doctor right away if you give your child more acetaminophen in a day than you were told, even if your child feels well.

• This drug may affect certain lab tests. Tell all of your child’s health care providers and lab workers that your child takes this drug.

• If your child is taking warfarin, talk with the doctor. Your child may need to have blood work checked more closely while taking it with this drug.

• Do not give this drug with other strong pain drugs or pain
patches without talking to your child’s doctor first.

- Long-term use of an opioid drug like this drug may lead to lower sex hormone levels. This may lead to signs like change in sex ability in males, no menstrual period in females, lowered interest in sex, or fertility problems. If any of these apply to your child, call your child’s doctor.

- This drug may raise the chance of seizures in some people, including people who have had seizures in the past. Talk to the doctor to see if your child has a greater chance of seizures while taking this drug.

- 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.

**If your child is pregnant:**

- This drug may cause harm to the unborn baby if your child takes it during pregnancy. If your child is pregnant or gets pregnant while taking this drug, call the doctor right away.

**Tablets:**

- If your child is allergic to sulfites, talk with your child’s doctor. Some products have sulfites in them.

**What are some side effects that I need to call my child’s 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 child’s doctor or get medical help right away if your child has 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.
- 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.
- Feeling very tired or weak.
- Very hard stools (constipation).
- Not able to pass urine or change in how much urine is passed.
- Fever or chills.
- Sore throat.
- Mood changes.
- Very bad headache.
- Noisy breathing.
- Feeling very sleepy.
- Any unexplained bruising or bleeding.
- Change in eyesight.
- Seizures.
- A very bad skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause very bad health problems that may not go away, and sometimes death. Get medical help right away if your child has signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in the mouth, throat, nose, or eyes.
- A very bad and sometimes deadly health problem called serotonin syndrome may happen if your child takes this drug with drugs for depression, migraines, or certain other drugs. Call the doctor right away if your child has agitation; change in balance; confusion; hallucinations; fever; fast or abnormal heartbeat; flushing; muscle twitching or stiffness; seizures; shivering or shaking; sweating a lot; very bad diarrhea, upset stomach, or throwing up; or very bad headache.
- Taking an opioid pain drug like this drug may lead to a rare but very bad adrenal gland problem. Call your child’s doctor right away if your child has very bad dizziness or passing out, very bad upset stomach or throwing up, or if your child feels less hungry, very tired, or very weak.
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 child’s doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

- Hard stools (constipation).
- Dizziness.
- Feeling sleepy.
- Belly pain.
- Upset stomach or throwing up.
- Sweating a lot.
- Feeling tired or weak.
- Headache.

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

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child’s doctor. Read all information given to you. Follow all instructions closely.

All products:

- Give this drug with or without food. Give with food if it
causes an upset stomach.

- Have your child drink lots of noncaffeine liquids every day unless told to drink less liquid by your child’s doctor.
- Your child will be watched closely to make sure your child does not misuse, abuse, or become addicted to this drug.

**All liquid products:**

- 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.

**Liquid (suspension):**

- Shake well before use.

**What do I do if my child misses a dose?**

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

**How do I store and/or throw out this drug?**
• Store at room temperature.
• Protect from light.
• Store in a dry place. Do not store in a bathroom.
• Keep all drugs in a safe place. Keep all drugs out of the reach of children and 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 child’s symptoms or health problems do not get better or if they become worse, call your child’s doctor.
• Do not share your child’s drug with others and do not give anyone else’s drug to your child.
• Keep a list of all your child’s drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your child’s doctor.
• Talk with your child’s doctor before giving your child any new drug, including prescription or OTC, natural products, or vitamins.
• Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child’s doctor, nurse, pharmacist, or other health care
provider.

- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

**Consumer Information Use and Disclaimer**

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine.

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If you have any questions or concerns, talk with a member of your healthcare team. You can reach them Monday through Friday from 9:00 AM to 5:00 PM at __________________________. After 5:00 PM, during the weekend, and on holidays, please call_________________________. If there’s no number listed, or you’re not sure, call 212-639-2000.

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