

Brightside Specialty Pharmacy

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Patient Education for ACETAMINOPHEN-COD #3 TABLET



Damages kidney/liver in excessive doses Avoid medicines containing same ingredient(s)
May be habit forming Avoid taking with other CNS depressant drugs or alcohol May cause
drowsiness or dizziness Use caution driving. Taking more than recommended dose may
cause respiratory arrest. Consult Dr/RPh about other APAP products. Risk of overdose. Birth
defect risk in early pregnancy/harm to newborn at term

Do not take more medicine than is recommended Avoid other medicines
containing the same drug May be habit forming Avoid alcohol/other drugs that
make you sleepy May make you drowsy or dizzy. Drive with caution Taking a
larger dose may cause breathing problems. Other acetaminophen use needs
doctor's approval. Discuss risks/benefits if woman of childbearing age

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

ACETAMINOPHEN/CODEINE - ORAL

(a-SEET-a-MIN-oh-fen/KOE-deen)

COMMON BRAND NAME(S):

Tylenol-Codeine, Vopac

WARNING:

Codeine has a risk for abuse and addiction, which can

lead to overdose and death. Codeine may also cause severe, possibly fatal, breathing problems. To lower your risk, your doctor should have you take the smallest dose of codeine that works, and take it for the shortest possible time. See also How to Use section for more information about addiction.

Ask your doctor or pharmacist if you should have naloxone available to treat opioid overdose. Teach your family or household members about the signs of an opioid overdose and how to treat it.

The risk for severe breathing problems is higher when you start this medication and after a dose increase, or if you take the wrong dose/strength. Taking this medication with alcohol or other drugs that can cause drowsiness or breathing problems may cause very serious side effects, including death. Also, other medications can affect the removal of codeine from your body, which may affect how codeine works. Be sure you know how to take this medication and what other drugs you should avoid taking with it. See also Drug Interactions section. Get medical help right away if any of these very serious side effects occur:

slow/shallow breathing, unusual lightheadedness, severe drowsiness/dizziness, difficulty waking up.

Keep this medicine in a safe place to prevent theft, misuse,

or abuse. If someone accidentally swallows this drug, get medical help right away.

One ingredient in this product is acetaminophen. Taking too much acetaminophen may cause serious (possibly fatal) liver disease. Adults should not take more than 4000 milligrams (4 grams) of acetaminophen a day. People with liver problems and children should take less acetaminophen. Ask your doctor or pharmacist how much acetaminophen is safe to take.

Do not use with any other drug containing acetaminophen without asking your doctor or pharmacist first. Acetaminophen is in many nonprescription and prescription medications (such as pain/fever drugs or cough-and-cold products). Check the labels on all your medicines to see if they contain acetaminophen, and ask your pharmacist if you are unsure.

Get medical help right away if you take too much acetaminophen (overdose), even if you feel well. Overdose symptoms may include nausea, vomiting, loss of appetite, sweating, stomach/abdominal pain, extreme tiredness, yellowing eyes/skin, and dark urine.

Daily alcohol use, especially when combined with acetaminophen, may damage your liver. Avoid alcohol.

Before using this medication, women of childbearing age should talk with their doctor(s) about the risks and benefits. Tell your doctor if you are pregnant or if you plan to become pregnant. During pregnancy, this medication should be used only when clearly needed. It may slightly increase the risk of birth defects if used during the first two months of pregnancy. Also, using it for a long time or in high doses near the expected delivery date may harm the unborn baby. To lessen the risk, take the smallest effective dose for the shortest possible time. Babies born to mothers who use this drug for a long time may develop severe (possibly fatal) withdrawal symptoms. Tell the doctor right away if you notice any symptoms in your newborn baby such as crying that doesn't stop, slow/shallow breathing, irritability, shaking, vomiting, diarrhea, poor feeding, or difficulty gaining weight.

Children younger than 18 years should not use products that contain codeine. Some children are more sensitive to codeine and have had very serious (rarely fatal) breathing problems such as slow/shallow breathing (see also Side Effects section). The risk is greater in children who are obese or have breathing problems,

or after certain surgeries (including tonsil/adenoid removal).
Talk with your doctor or pharmacist about the risks and benefits of this medication.

USES:

See also Warning section.

This combination medication is used to help relieve mild to moderate pain. It contains an opioid pain reliever (codeine) and a non-opioid pain reliever (acetaminophen). Codeine works in the brain to change how your body feels and responds to pain. Acetaminophen can also reduce a fever.

HOW TO USE:

See also Warning section.

Read the Medication Guide provided by your pharmacist before you start taking acetaminophen/codeine and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth as directed by your doctor. You may take this drug with or without food. If you have nausea, it may help to take this drug with food. Ask your doctor or pharmacist about other ways to decrease nausea (such as lying down for 1 to 2 hours with as little head movement as possible).

If you are using a liquid form of this medication, use a medication measuring device to carefully measure the prescribed dose. Do not use a household spoon because you may not get the correct dose. If you are taking the suspension, shake the bottle well before each dose.

The dosage is based on your medical condition and response to treatment. Do not increase your dose, take the medication more frequently, or take it for a longer time than prescribed.

Properly stop the medication when so directed.

Pain medications work best if they are used as the first signs of pain occur. If you wait until the pain has worsened, the medication may not work as well.

If you have ongoing pain (such as due to cancer), your doctor may direct you to also take long-acting opioid medications. In that case, this medication might be used for sudden (breakthrough) pain only as needed. Other pain relievers (such as naproxen, ibuprofen) may also be prescribed with this medication. Ask your doctor or pharmacist about using this product safely with other drugs.

Suddenly stopping this medication may cause withdrawal, especially if you have used it for a long time or in high doses. To prevent withdrawal, your doctor may lower your dose slowly. Tell your doctor or pharmacist right away if you have any withdrawal symptoms such as restlessness, mental/mood changes (including anxiety, trouble sleeping, thoughts of suicide), watering eyes, runny nose, nausea, diarrhea, sweating, muscle aches, or sudden changes in behavior.

When this medication is used for a long time, it may not work as well. Talk with your doctor if this medication stops working well.

Though it helps many people, this medication may sometimes cause addiction. This risk may be higher if you have a substance use disorder (such as overuse of or addiction to drugs/alcohol). Take this medication exactly as prescribed to lower the risk of addiction. Ask your doctor or pharmacist for more details.

Tell your doctor if your pain does not get better or if it gets worse.

SIDE EFFECTS:

See also Warning section.

Nausea, vomiting, constipation, lightheadedness, dizziness, or drowsiness may occur. Some of these side effects may decrease after you have been using this medication for a while. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

To prevent constipation, eat dietary fiber, drink enough water, and exercise. You may also need to take a laxative. Ask your pharmacist which type of laxative is right for you.

To reduce the risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position.

Remember that this medication has been prescribed because your doctor has judged that 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 right away if you have any serious side effects, including: interrupted breathing during sleep (sleep apnea), mental/mood changes (such as agitation, depression, hallucinations), severe stomach/abdominal pain, difficulty urinating, fast/slow heartbeat, vision changes, signs of your adrenal glands not working well (such as loss of appetite, unusual tiredness, weight loss).

Get medical help right away if you have any very serious side effects, including: fainting, seizure.

Codeine is changed into a strong opioid drug (morphine) in your body. In some people, this change happens faster and more completely than usual, which increases the risk of very serious side effects. Get medical help right away if you notice any of the following: slow/shallow breathing, severe drowsiness/difficulty waking up, confusion.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

See also Warning section.

Before taking this product, tell your doctor or pharmacist if you are allergic to acetaminophen or codeine; or to other opioid pain medications (such as morphine); or if you have any other allergies. This product may contain inactive ingredients (such as metabisulfite), which can cause allergic reactions or other

problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: brain disorders (such as head injury, tumor, seizures), breathing problems (such as asthma, sleep apnea, chronic obstructive pulmonary disease-COPD), kidney disease, liver disease, mental/mood disorders (such as confusion, depression), personal or family history of a substance use disorder (such as overuse of or addiction to drugs/alcohol), obesity, stomach/intestinal problems (such as blockage, constipation, diarrhea due to infection, paralytic ileus), difficulty urinating (such as due to enlarged prostate), gallbladder disease, disease of the pancreas (pancreatitis).

This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

Liquid products may contain sugar and alcohol. Caution is advised if you have diabetes, alcohol dependence, liver disease, or any other condition that requires you to limit/avoid these substances in your diet. Ask your doctor or pharmacist about using this product safely.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Older adults may be more sensitive to the side effects of this drug, especially confusion, dizziness, drowsiness, and slow/shallow breathing.

During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Discuss the risks and benefits with your doctor.

This medication passes into breast milk and may have undesirable effects on a nursing infant, such as unusual sleepiness, difficulty feeding, trouble breathing, or unusual limpness. Breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

See also Warning section.

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: certain pain medications (mixed opioid agonist-antagonists such as butorphanol, nalbuphine, pentazocine), naltrexone, samidorphan.

The risk of serious side effects (such as slow/shallow breathing, severe drowsiness/dizziness) may be increased if this medication is taken with other products that may also cause drowsiness or breathing problems. Tell your doctor or pharmacist if you are taking other products such as other opioid pain or cough relievers (such as morphine, hydrocodone), alcohol, marijuana (cannabis), drugs for sleep or anxiety (such as

alprazolam, lorazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), or antihistamines (such as cetirizine, diphenhydramine).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

Other medications can affect the removal of acetaminophen/codeine from your body, which may affect how acetaminophen/codeine works. Examples include azole antifungals (such as ketoconazole), bupropion, fluoxetine, macrolide antibiotics (such as erythromycin), HIV medications (such as ritonavir), levoketoconazole, paroxetine, quinidine, rifamycins (such as rifabutin, rifampin), certain drugs used to treat seizures (such as carbamazepine, phenytoin), among others.

This medication may interfere with certain laboratory tests (including amylase/lipase levels), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, give them naloxone if available, then call 911. If the person is awake and has no symptoms, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center.

Symptoms of overdose may include:

slow/shallow breathing, nausea,

vomiting, loss of appetite, sweating, stomach/abdominal pain, slow heartbeat, extreme tiredness, yellowing eyes/skin, dark urine, coma.

NOTES:

Do not share this medication with others. Sharing it is

against the law.

This medication has been prescribed for your current condition only. Do not use it later for another condition unless your doctor directs you to do so. A different medication may be necessary in that case.

MISSED DOSE:

If you are taking this medication on a regular

schedule and you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Different brands of this medication have different storage needs. Check the product package for instructions on how to store your brand, or ask your pharmacist. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product

when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

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