

**ACETAMINOPHEN- acetaminophen tablet, coated**  
**Central Texas Community Health Centers**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Acetaminophen Tablets**

***Drug Facts***

**Active ingredient (in each tablet)**

Acetaminophen 325 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches
  - backache
  - minor pain of arthritis
  - the common cold
  - toothache
  - premenstrual and menstrual cramps
- temporarily reduces fever

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 12 tablets in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

**Do not use** with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

**Ask a doctor before use if the user has** liver disease.

**Ask a doctor or pharmacist before use if the user is** taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days in adults and in children 12 years and over
- pain gets worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning**

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- do not take more than directed (see overdose warning)

adults and children 12 years and over	<ul style="list-style-type: none"><li>take 2 tablets every 4 to 6 hours while symptoms last</li><li>do not take more than 12 tablets in 24 hours</li></ul>
children 6-11 years	<ul style="list-style-type: none"><li>take 1 tablet every 4 to 6 hours while symptoms last</li><li>do not take more than 5 tablets in 24 hours</li></ul>
children under 6 years	<ul style="list-style-type: none"><li>do not use this adult product in children under 6 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage</li></ul>

**Other information**

- store between 20°-25°C (68°-77°F)
- retain carton for complete product information

**Inactive ingredients**

crospovidone, methylparaben, povidone, pregelatinized starch, propylparaben, sodium starch glycolate, stearic acid

**Distributed By McKesson**  
**One Post Street, San Francisco, CA 94104**

**PRINCIPAL DISPLAY PANEL - 325 MG Tablet Bottle Label**

CommUnityCare Federally Qualified Health Centers

ACETAMINOPHEN  
325MG #30 TABS

Date:

Name:

Dr.

TAKE AS DIRECTED.

123456

1/1/01

ACETAMINOPHEN 325mg #30 NDC 76413-301-30

Batch: 123456

Lot: 123456

Exp: 1/1/01

SUNMARK

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

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**ACETAMINOPHEN**

acetaminophen tablet, coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76413-301(NDC:49348-973)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	M2A3;57344
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-301-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	12/13/2012	

**Labeler** - Central Texas Community Health Centers (079674019)

### Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-301) , RELABEL(76413-301)

Revised: 3/2016

Central Texas Community Health Centers