

**PAIN RELIEF REGULAR STRENGTH- acetaminophen tablet**  
**AMERICAN SALES COMPANY**

*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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**1001 - CAR - 2018-1229**

***Drug Facts***

**Active ingredient (in each tablet)**

Acetaminophen 325 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

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

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

**Allergy alert**

acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**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.
- if the user is allergic to acetaminophen or any of the inactive ingredients in this product

**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
- 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**

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 10 tablets in 24 hours</li><li>▪ do not use for more than 10 days unless directed by a doctor</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><li>▪ do not use for more than 5 days unless directed by a doctor</li></ul>
children under 6 years	<ul style="list-style-type: none"><li>▪ ask a doctor</li></ul>

**Other information**

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

**Inactive ingredients**

povidone, pregelatinized starch, sodium starch glycolate, stearic acid

**PRINCIPAL DISPLAY PANEL**

NDC 41520-606-02

CareOne®

Compare to the active ingredient in Tylenol® Regular Strength Tablets\*

Regular Strength

Acetaminophen

325 mg

Pain Reliever/Fever Reducer

• Contains No Aspirin

Our Pharmacists Recommend

100 Tablets

INK AND COATING FREE FOR LOT AND EXPIRATION STAMPING

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DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

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- if the user is allergic to acetaminophen or any of the inactive ingredients in this product

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**Drug Facts (continued)**  
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CAREone®  
Compare to the active ingredient in Tylenol® Regular Strength Tablets\*  
Regular Strength  
**ACETAMINOPHEN**  
325 mg  
Pain Reliever/Fever Reducer  
• Contains No Aspirin  
Actual Size  
100 TABLETS  
OUR PHARMACISTS RECOMMEND

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NDC 41520-606-02  
Compare to the active ingredient in Tylenol® Regular Strength Tablets\*  
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OUR PHARMACISTS RECOMMEND

**PAIN RELIEF REGULAR STRENGTH**

acetaminophen tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-606
<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>
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED 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:41520-606-02	1 in 1 CARTON	08/01/2010	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part343	08/01/2010	

**Labeler** - AMERICAN SALES COMPANY (809183973)