

ACETAMINOPHEN-APAP 8 HOUR- acetaminophen tablet, film coated, extended release
American Sales Company

Drug Facts

ACTIVE INGREDIENT (IN EACH CAPLET)

Acetaminophen USP, 650 mg

PURPOSE

Pain reliever/fever reducer

USES

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - headache
 - minor pain of arthritis
 - backache

- temporarily reduces fever

WARNINGS

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 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.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have

Liver disease.

Ask a doctor or pharmacist before use if you are

Taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- 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">▪ take 2 caplets every 8 hours with water▪ swallow whole - do not crush, chew, split or dissolve▪ do not take more than 6 caplets in 24 hours▪ do not use for more than 10 days unless directed by a doctor
children under 12 years	<ul style="list-style-type: none">▪ do not use

OTHER INFORMATION

- store at 20 - 25° C (68 - 77° F). Avoid excessive heat 40° C (104° F).
- see end panel for batch number and expiration date
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**

INACTIVE INGREDIENTS

Croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

QUESTIONS?

Call **1-888-423-0139**

PRINCIPAL DISPLAY PANEL

Compare to the Active Ingredient in Tylenol® 8 Hour**

CAREONE®

Use only as directed.

Lasts up to 8 HOUR

PAIN RELIEF

Acetaminophen Extended-Release Tablets, USP 650 mg

PAIN RELIEVER · FEVER REDUCER

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

For Up To 8 Hour Relief of Minor Muscle Aches & Pain

24 CAPLETS* 650 mg Each

* Capsule-Shaped Tablets

DISTRIBUTED BY: AMERICAN SALES COMPANY

5089223/R0811

Non Varnish Area

Batch No. 415201316968

Expiration Date: 8

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

Compare to the Active Ingredient in Tylenol® 8 Hour**

CAREONE®

Lasts up to **8 HOUR PAIN RELIEF**

Acetaminophen Extended-Release Tablets, USP 650 mg

PAIN RELIEVER - FEVER REDUCER

For Up To 8 HOUR Relief of Minor Muscle Aches & Pain

Use only as directed.

24 CAPLETS*
650 mg each

*Capsule-Shaped Tablets

R0811

Contains No Aspirin

Keep the carton. It contains important information.

**This product is not manufactured or distributed by McKel Consumer Healthcare, Inc., owner of the registered trademark Tylenol® 8 Hour.

GLUTEN FREE

DISTRIBUTED BY: AMERICAN SALES COMPANY
4201 WALDEN AVENUE, LANCASTER, NY 14086
©2011 S&S Brands, Inc.
Quality guaranteed or your money back.

5089223

Drug Facts (continued)

Directions

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

adults & children 12 years & over

- take 2 caplets every 8 hours with water
- swallow whole – do not crush, chew or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

children under 12 years

- ask a doctor

Other information

- store at 20 - 25° C (68 - 77° F). Avoid excessive heat 40° C (104° F).
- see end panel for batch number and expiration date

Inactive ingredients

croscarmellose sodium, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

Questions? call 1-800-406-7984

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Drug Facts (continued)

- if you are allergic to acetaminophen or any of the inactive ingredients in this product.
- if you have difficulty swallowing large tablets or capsules. People over 65 may have difficulty swallowing these tablets.

Ask a doctor before use if you have liver disease.

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- 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.

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5089223

Drug Facts

Active ingredient (in each caplet) Acetaminophen USP 650 mg...fever reducer

Purpose Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - headache
 - minor pain of arthritis
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 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.

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ACETAMINOPHEN-APAP 8 HOUR
acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-336	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg	
Inactive Ingredients				
	Ingredient Name	Strength		
	CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
	HYPROMELLOSES (UNII: 3NXW29V3WO)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
	POVIDONE (UNII: FZ989GH94E)			
	STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
	STEARIC ACID (UNII: 4ELV7Z65AP)			
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
Product Characteristics				
Color	white	Score	no score	
Shape	OVAL (Capsule Shaped)	Size	9mm	
Flavor		Imprint Code	cor116	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-336-23	24 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA076200	04/30/2002		

Labeler - American Sales Company (809183973)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 1/2013

American Sales Company