

**ACETAMINOPHEN 8 HOUR- acetaminophen tablet, film coated, extended release  
Supervalu Inc.**

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**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
  - backache
  - 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.
- 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)**

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

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**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 **1-877-932-7948**

**PRINCIPAL DISPLAY PANEL**

**equaline®**

**compare to Tylenol® 8 Hour active ingredient\***

**NDC 41163-336-01**

**use only as directed**

**lasts up to 8 hours**

**acetaminophen extended-release tablets, USP 650 mg**

**100 caplets\*\***

**pain reliever/fever reducer**

**650 mg each**

**for up to 8 hour relief of minor muscle aches and pain**

**(\*\*capsule-shaped tablets)**


**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

**DISTRIBUTED BY SUPERVALU INC.**

COATING FREE AREA  
NON-IMPRIINTED AREA

Batch No. 0 41163 41302 3  
Expiration Date

31  
000000  
0000



compare to Tylenol®  
8 Hour active ingredient\*

NDC 41163-336-01

use only as directed  
lasts up to 8 hours

## acetaminophen

extended-release tablets, USP 650 mg  
pain reliever/fever reducer

for up to 8 hour relief of minor muscle aches and pain

**100 caplets\*\***  
650 mg each  
(\*capsule-shaped tablets)


**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

COATING FREE AREA

0 7 5 9 6 0 5

COATING FREE AREA

5 0 9 8 5 7 0



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COATING FREE AREA

1 8 1 9 7 8



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**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

COATING FREE AREA

0 7 5 9 6 0 5

COATING FREE AREA

1 8 1 9 7 8

**Drug Facts (continued)**

for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- take 2 caplets every 8 hours with adults and children 12 years and over
- 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
- do not use

children under 12 years

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

**Questions?** call 1-877-932-7948

**Contains No Aspirin**

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, a division of the McNeil Company, registered trademark, Tylenol® is The Tylenol Company.

DISTRIBUTED BY SUPervalU INC.  
EDEN PRAIRIE, MN 55344 USA  
Contact us at 1-877-932-7948, or  
[www.supervalu-ourvalubrand.com](http://www.supervalu-ourvalubrand.com)

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COATING FREE AREA

0 7 5 9 6 0 5

# ACETAMINOPHEN 8 HOUR

acetaminophen tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41163-336	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	CROSCARMELLOSE 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)			
<b>Product Characteristics</b>				
<b>Color</b>	white	<b>Score</b>	no score	
<b>Shape</b>	OVAL (Capsule Shaped)	<b>Size</b>	19mm	
<b>Flavor</b>		<b>Imprint Code</b>	cor116	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:41163-336-01	1 in 1 CARTON		
1		100 in 1 BOTTLE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA076200	08/13/2013		

**Labeler** - Supervalu Inc. (006961411)

**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(41163-336)

Revised: 9/2013

Supervalu Inc.