

**PAIN RELIEF RAPID RELEASE GELCAPS EXTRA STRENGTH- acetaminophen tablet,  
coated  
Safeway**

*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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**SIG - 1170 - 2019-1007**

***Drug Facts***

**Active ingredient (in each gelcap)**

Acetaminophen 500 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 you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 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 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"><li>• take 2 gelcaps every 6 hours while symptoms last</li><li>• do not take more than 6 gelcaps in 24 hours, unless directed by a doctor</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>• ask a doctor</li></ul>

**Other information**

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

**Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, D&C red #33, edible ink, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, pregelatinized starch, stearic acid, titanium dioxide

**PRINCIPAL DISPLAY PANEL**

COMPARE TO

Tylenol® Rapid Release Gelcaps

Active ingredient\*

NDC 21130-270-01

Signature Care™

Quality Guaranteed

Extra Strength

Pain Relief

Acetaminophen 500mg

Pain Reliever.Fever Reducer

Aspirin free

Easy to swallow/rapid release

RAPID RELEASE GELCAPS

24 GELCAPS

INK AND COATING FREE  
FOR LOT AND  
EXPIRATION STAMPING

5 09282 21130 78260 3

S4972 RD 18187

NC

**Drug Facts (continued)**  
**Directions** ■ do not take more than directed (see overdose warning)  
adults and children 12 years and over ■ take 2 gelcaps every 6 hours while symptoms last  
■ do not take more than 6 gelcaps in 24 hours, unless directed by a doctor  
■ do not use for more than 10 days unless directed by a doctor  
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■ store between 20-25°C (68-77°F)  
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**Inactive ingredients** colloidal silicon dioxide, croscarmellose sodium, D&C red #33, edible ink, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, pregelatinized starch, stearic acid, titanium dioxide

DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING  
\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Rapid Release Gelcaps.

**COMPARE TO**  
Tylenol® Rapid Release Gelcaps  
active ingredient\*  
NDC 21130-270-01

Signature care™  
Quality Guaranteed

**Extra Strength Pain Relief**  
**ACETAMINOPHEN 500 mg**  
Pain Reliever/Fever Reducer

• Aspirin free  
• Easy to swallow/rapid release

Actual Size  
RAPID RELEASE GELCAPS  
24 GELCAPS

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**Purpose**  
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■ the common cold ■ headache  
■ backache ■ minor pain of arthritis  
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■ premenstrual and menstrual cramps  
■ temporarily reduces fever

**Warnings**  
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■ with other drugs containing acetaminophen  
■ 3 or more alcoholic drinks every day while using this product  
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■ skin reddening ■ blisters ■ rash  
If a skin reaction occurs, stop use and seek medical help right away.

**Drug Facts (continued)**  
**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.

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**100% GUARANTEED**  
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## PAIN RELIEF RAPID RELEASE GELCAPS EXTRA STRENGTH

acetaminophen tablet, coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21130-270
<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	500 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	gray (red and light blue ends)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	G1
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-270-01	1 in 1 CARTON	08/05/2015	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:21130-270-13	225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/05/2015	

**Labeler** - Safeway (009137209)

Revised: 10/2019

Safeway