

**ACETAMINOPHEN- acetaminophen tablet, film coated**  
**Safrel Pharmaceuticals, LLC.**

*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 Rapid Release Caplets**

**Active ingredient (in each caplet)**

Acetaminophen 500 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 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 have ever had an allergic reaction to this product or any of its ingredients

**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 caplets every 6 hours while symptoms last</li><li>• do not take more than 6 caplets 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	ask a doctor

**Other information**

- store at 20-25 °C (68-77 °F)

**Inactive ingredients**

carnauba wax, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

## Questions or comments?

1--844-384-3723

## Package/Label Principal Display Panel

Compare to the active ingredient in Tylenol<sup>®</sup> Rapid Release Gels

Rapid Release Caplets

EXTRA STRENGTH

Acetaminophen Caplets, 500 mg

Pain reliever;

Fever reducer

Aspirin free

For Adults

RAPID RELEASE

DYE FREE

400 Count

<p><b>Drug Facts (continued)</b></p> <p>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.</p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. <b>Overdose warning:</b> 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.</p> <p><b>Directions</b></p> <p>■ do not take more than directed (see overdose warning)</p> <table border="0"> <tr> <td>adults and children 12 years and over</td> <td>■ take 2 caplets every 6 hours while symptoms last</td> </tr> <tr> <td></td> <td>■ do not take more than 6 caplets in 24 hours, unless directed by a doctor</td> </tr> <tr> <td>children under 12 years</td> <td>■ do not use for more than 10 days unless directed by a doctor</td> </tr> <tr> <td></td> <td>■ ask a doctor</td> </tr> </table> <p><b>Other information</b></p> <p>■ store at 20-25°C (68-77°F)</p> <p><b>Inactive ingredients</b></p> <p>canuaba wax, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid</p> <p><b>Questions or Comments?</b> 1-844-384-3723</p>	adults and children 12 years and over	■ take 2 caplets every 6 hours while symptoms last		■ do not take more than 6 caplets in 24 hours, unless directed by a doctor	children under 12 years	■ do not use for more than 10 days unless directed by a doctor		■ ask a doctor	<p>*Compare to Tylenol<sup>®</sup> Rapid Release Gels Active Ingredient</p> <p>NDC 71309-077-04</p> <p><b>Safrel<sup>®</sup></b></p> <p>Extra Strength <b>NO-PAIN</b> Rapid Release Caplets</p> <p><b>Acetaminophen</b> 500 mg</p> <p>Pain reliever/Fever reducer Fast Relief For Adults Aspirin Free</p> <p><b>RAPID RELEASE</b></p> <p><b>DYE FREE</b></p> <p>400 CAPLETS-500 mg Each actual size</p>	<p><b>Drug Facts</b></p> <table border="1"> <tr> <th>Active Ingredient (in each caplet)</th> <th>Purpose</th> </tr> <tr> <td>Acetaminophen USP 5 mg</td> <td>Pain Reliever/Fever Reducer</td> </tr> </table> <p><b>Uses</b> ■ 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</p> <p><b>Warnings</b> Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4,000 mg of acetaminophen 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</p> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Do Not Use</b> ■ 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 have ever had an allergic reaction to this product or any of its ingredients</p> <p>Ask a doctor before use if you have liver disease</p> <p>Ask a doctor before use if you are taking the blood thinning drug warfarin</p> <p>Distributed By: Safrel Pharmaceuticals Bridgewater, NJ 08807 USA www.safrelpharma.com</p> <p><b>GLUTEN FREE</b></p> <p>Lot: _____ EXP: _____</p> <p>3 71309 07704 9</p>	Active Ingredient (in each caplet)	Purpose	Acetaminophen USP 5 mg	Pain Reliever/Fever Reducer
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DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

## ACETAMINOPHEN

acetaminophen tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71309-077
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	500
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-077-04	400 in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/07/2020	

**Labeler** - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 6/2021

Safrel Pharmaceuticals, LLC.