

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.

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">• take 2 caplets every 6 hours while symptoms last• do not take more than 6 caplets in 24 hours, unless directed by a doctor• 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)

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[®] Rapid Release Gels

Rapid Release Caplets

EXTRA STRENGTH

Acetaminophen Caplets, 500 mg

Pain reliever;

Fever reducer

Aspirin free

For Adults

RAPID RELEASE

DYE FREE

100 CAPLETS

<p>Drug Facts</p> <p>Active ingredient (in each caplet) Acetaminophen USP 500mg..... Pain reliever/ Fever reducer</p> <p>Purpose</p> <p>Uses temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> headache muscular aches backache minor pain of arthritis the common cold toothache premenstrual and menstrual cramps temporarily reduces fever </p> <p>Warnings Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take <ul style="list-style-type: none"> 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 Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: <ul style="list-style-type: none"> skin reddening blisters rash </p>	<p>*Compare to Tylenol® Rapid Release Gels Active Ingredient</p> <p>NDC 71309-077-10</p> <p>Safrel</p> <p>NO-PAIN Extra Strength Rapid Release</p> <p>500 MG</p> <p>ACETAMINOPHEN</p> <ul style="list-style-type: none"> Pain Reliever Fever Reducer For Adults Aspirin Free <p>DYE FREE</p> <p>100 Caplets</p>	<p>Drug Facts (continued)</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Do Not Use</p> <ul style="list-style-type: none"> 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>Ask a doctor before use if you have liver disease</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</p> <p>Lot. Exp.</p>
--	---	--

PEEL BACK HERE ▶

<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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 <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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.</p>	<p>Directions</p> <ul style="list-style-type: none"> do not take more than directed (see overdose warning) <table border="1"> <tr> <td>adults and children 12 years and over</td> <td>take 2 caplets every 6 hours while symptoms last</td> </tr> <tr> <td>children under 12 years</td> <td>do not take more than 6 caplets in 24 hours, unless directed by a doctor unless directed by a doctor</td> </tr> </table>	adults and children 12 years and over	take 2 caplets every 6 hours while symptoms last	children under 12 years	do not take more than 6 caplets in 24 hours, unless directed by a doctor unless directed by a doctor	<p>Other information ■ store at 20-25°C (68-77°F).</p> <p>Inactive ingredients carnauba wax, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid</p>	<p>Questions or comments ? 1-844-384-3723</p> <p>TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING</p> <p>Distributed By: Safrel Pharmaceuticals Bridgewater, NJ 08807 USA www.safrelpharma.com</p>
adults and children 12 years and over	take 2 caplets every 6 hours while symptoms last						
children under 12 years	do not take more than 6 caplets in 24 hours, unless directed by a doctor unless directed by a doctor						

ACETAMINOPHEN

acetaminophen tablet, film coated

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
--	---------------	--------

Inactive Ingredients

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

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-077-10	100 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: 4/2020

Safrel Pharmaceuticals, LLC.