

ACETAMINOPHEN- acetaminophen tablet, extended release
Safrel Pharmaceuticals, LLC.

Acetaminophen Extended Release Tablets 650 mg

ACTIVE INGREDIENT (IN EACH CAPLET)

Acetaminophen USP, 650 mg

PURPOSE

Pain reliever/fever reducer

USES

For **Arthritis Pain label**

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - premenstrual and menstrual cramps
 - the common cold
 - headache
 - toothache
- temporarily reduces fever

For **Muscle Aches & Pain label**

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - backache
 - minor pain of arthritis
 - toothache
 - premenstrual and menstrual cramps
 - headache
 - the common cold
- 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 everyday 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 drugs 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 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

For Arthritis Pain Label

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

• take 2 caplets every 8 hours with water

adults	<ul style="list-style-type: none"> • 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
under 18 years of age	<ul style="list-style-type: none"> • ask a doctor

For Muscle Ache and Pain label

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

adults and children 12 years of age 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 between 20-25°C (68-77°F)
- **do not use if foil inner seal is broken or missing.**

INACTIVE INGREDIENTS

hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

QUESTIONS OR COMMENTS ?

Contact 1-844-384-3723 Mon-Fri 8:00 AM EST to 5:00 PM PST.

PRINCIPAL DISPLAY PANEL

100 Count



Dist. by: Safrel Pharmaceuticals
 1200 Route 22 East, Suite 2000
 Bridgewater, NJ 08807
 (944) 384-3723
 www.safrel.com

Drug Facts (continued)
 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 ■ 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

under 18 years of age ■ ask a doctor

Other information ■ store at 20-25°C (68-77°F)

Inactive ingredients
 hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or comments? 1-800-384-3723

DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.



ACETAMINOPHEN

Extended-Release Tablets • 650 mg

Pain Reliever / Fever Reducer

LASTS UP TO 8 HOURS
 for the Temporary Relief
 of Minor Arthritis Pain

100 CAPLETS / 650 MG EACH

NDC 71309-011-10
 COMPARE TO TYLENOL®
 8HR ARTHRITIS PAIN
 ACTIVE INGREDIENT.

DO NOT USE WITH
 OTHER MEDICINES
 CONTAINING
 ACETAMINOPHEN

Drug Facts
Active ingredient (in each caplet) **Purpose**
 Acetaminophen 650 mg Pain reliever/fever reducer

Uses ■ temporary reliefs minor aches and pains due to:
 ■ minor pain of arthritis ■ muscular aches ■ backache
 ■ premenstrual and menstrual cramps ■ the common cold
 ■ headache ■ toothache ■ 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
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.

400 Count



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 Bridgewater, NJ 08807
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Drug Facts (continued)
 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 ■ 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

under 18 years of age ■ ask a doctor

Other information ■ store at 20-25°C (68-77°F)

Inactive ingredients
 hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or comments? 1-800-384-3723

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ACETAMINOPHEN

Extended-Release Tablets • 650 mg

Pain Reliever / Fever Reducer

LASTS UP TO 8 HOURS
 for the Temporary Relief
 of Minor Arthritis Pain

400 CAPLETS / 650 MG EACH

NDC 71309-011-04
 COMPARE TO TYLENOL®
 8HR ARTHRITIS PAIN
 ACTIVE INGREDIENT.

DO NOT USE WITH
 OTHER MEDICINES
 CONTAINING
 ACETAMINOPHEN

Drug Facts
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ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-011
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
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G650
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-011-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/17/2022	
2	NDC:71309-011-04	400 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	04/18/2019	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 5/2022

Safrel Pharmaceuticals, LLC.