ACETAMINOPHEN- acetaminophen tablet, film coated, extended release
Granules USA, Inc.

---

8 Hour
Arthritis Pain
Acetaminophen Extended-release Tablets USP, 650 mg
Pain Reliever/Fever Reducer
For the Temporary Relief of Minor Arthritis Pain

Active ingredient

(in each caplet)
Acetaminophen USP, 650 mg

Purpose

Pain reliever/fever reducer

Uses

■ 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

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

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

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

■ d **o 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 between 20-25°C (68-77°F)

■ **do not use if foil inner seal is broken or missing**

Inactive ingredients

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

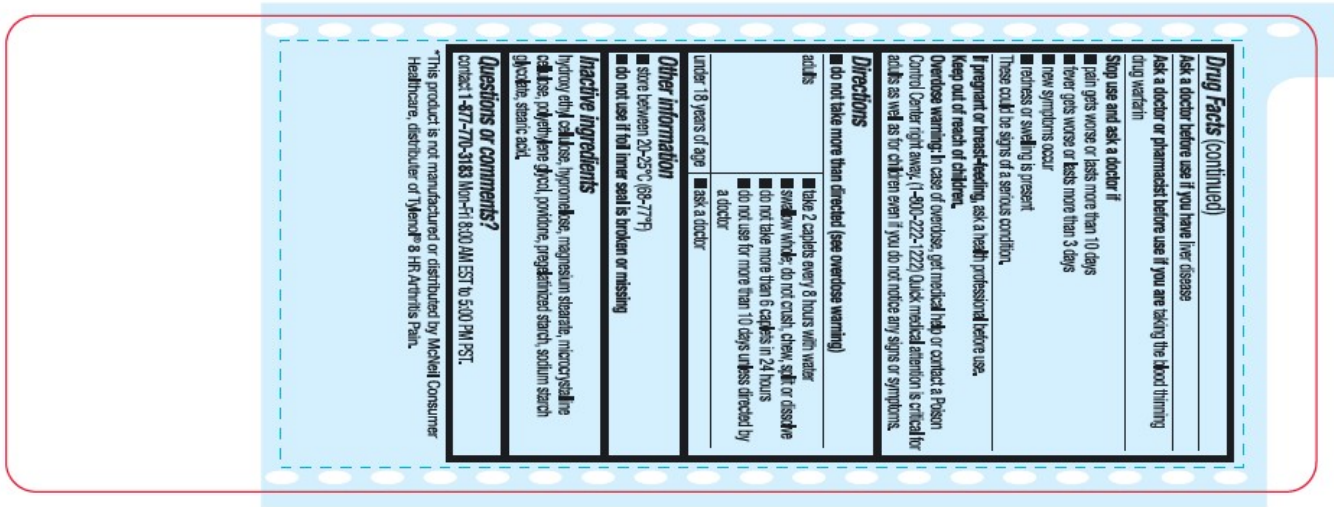
Questions or comments?

Contact **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

Acetaminophen Extended Release Tablets 650 mg, 100ct and 24 ct

I,

Inside (adhesive side)



Drug Facts (continued)

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)

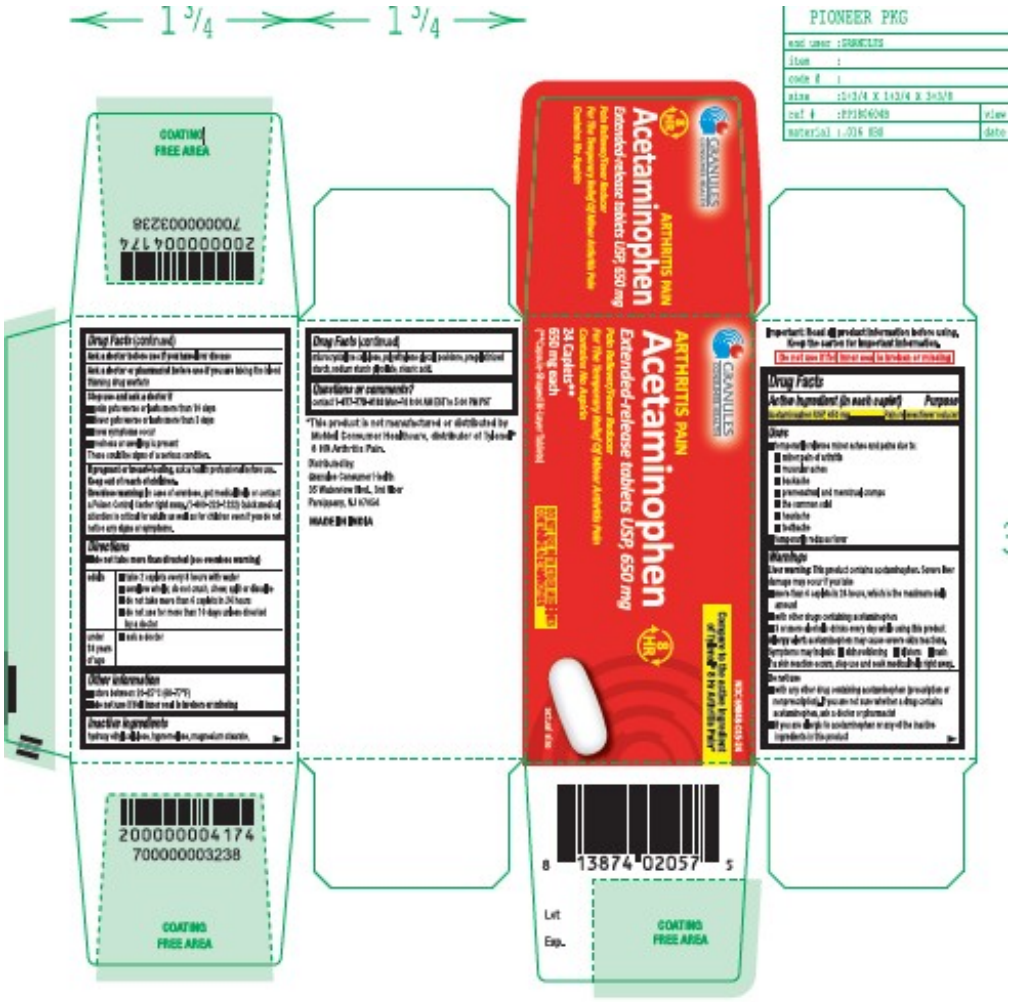
adults	■ take 2 caplets every 8 hours with water ■ swallow whole; do not crush, chew, split or dissolve ■ do not take more than 6 caplets in 24 hours ■ do not use for more than 10 days unless directed by a doctor
under 18 years of age	■ ask a doctor

Other information
- store between 20-25°C (68-77°F)
- do not use if foil inner seal is broken or missing

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

Questions or comments?
contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributer of Tylenol® 8 HR Arthritis Pain.



ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69848-015
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**
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white (White to off white colored)	**Score**	no score
Shape	OVAL (Capsule shaped, biconvex intact film coated tablets)	**Size**	19mm
Flavor		**Imprint Code**	G;650
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-015-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/31/2019	
2	NDC:69848-015-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	12/31/2019	

Labeler - Granules USA, Inc. (137098864)

Revised: 12/2024 Granules USA, Inc.