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

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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

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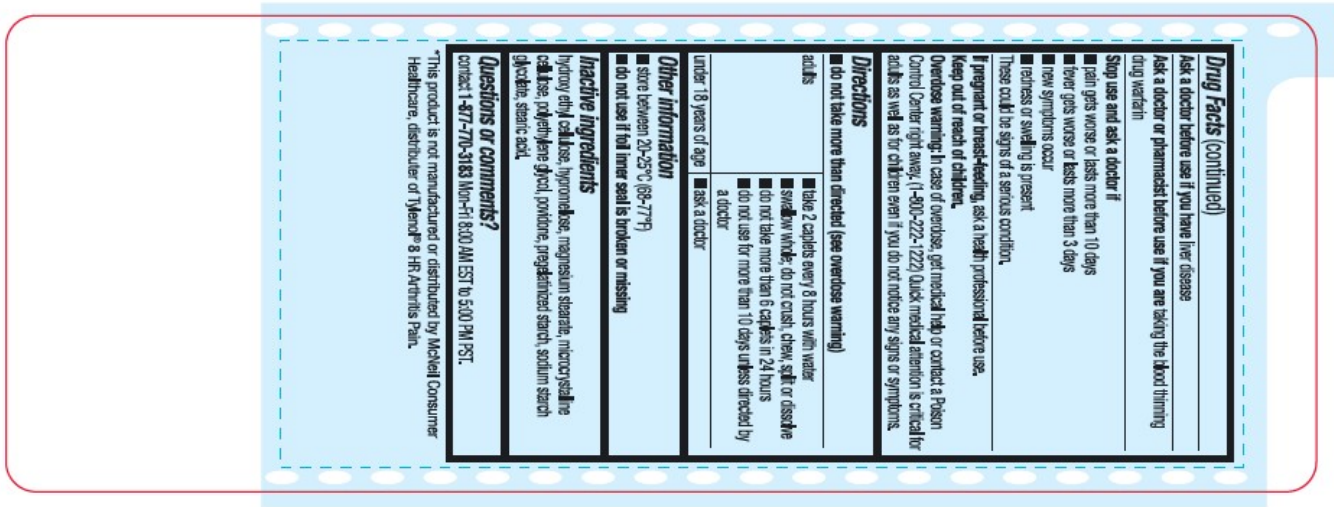
Inside (adhesive side)



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.

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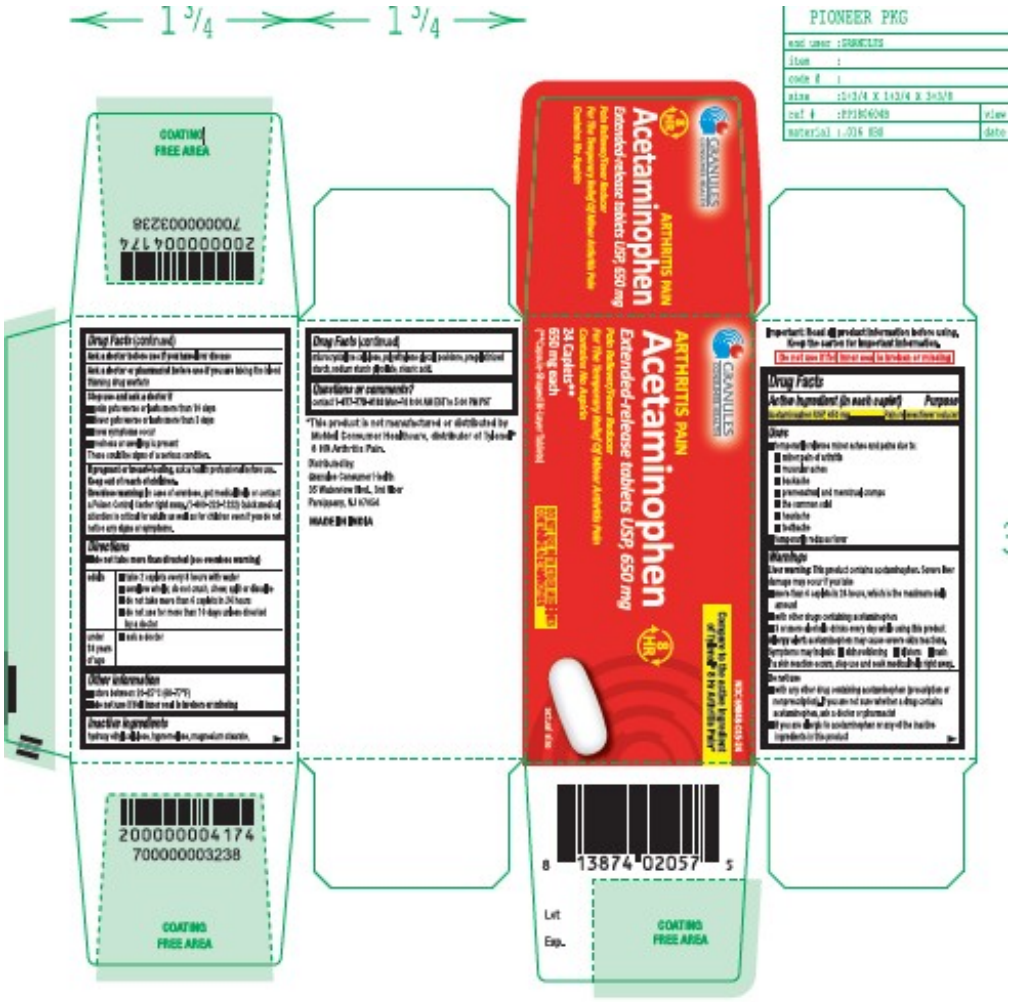
*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributer of Tylenol® 8 HR Arthritis Pain.



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: 12/2023 Granules USA, Inc.