MEDLINE- acetaminophen tablet, extended release
Medline Industries, LP

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197 650mg Extended Release Acetaminophen Tablets

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

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
These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a 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)

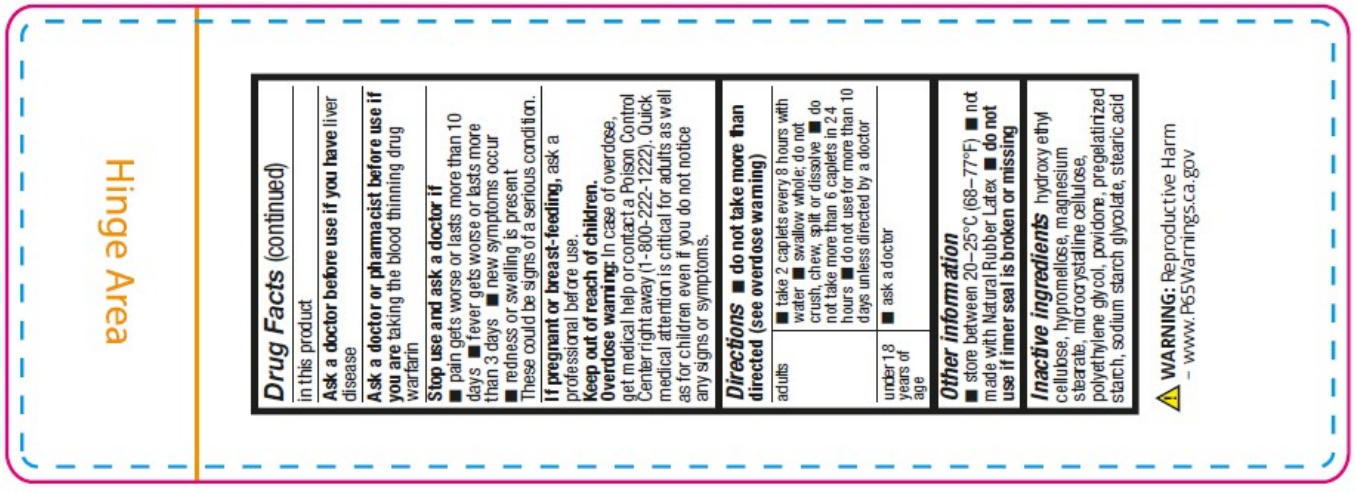
■ not made with Natural Rubber Latex

■ **do not use if 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

Label



MEDLINE

acetaminophen tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53329-197
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
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
POVIDONE (UNII: FZ989GH94E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	**Score**	score with uneven pieces
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	G650
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-197-29	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	07/01/2024	

Labeler - Medline Industries, LP (025460908)

Registrant - Medline Industries, LP (025460908)

Revised: 7/2024 Medline Industries, LP