PAIN RELIEF EXTRA STRENGTH- acetaminophen tablet, coated
Chain Drug Marketing Association

QCH - 1004 - 2019-1007

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

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

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.

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	• 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 between 20-25°C (68-77°F)
- retain carton for complete product information

Inactive ingredients

hypromellose, mineral oil, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 63868-084-50

QUALITY CHOICE

†Compare to the Active Ingredient in TYLENOL® Extra Strength Caplets

Extra Strength

Pain Relief

Pain Reliever / Fever Reducer

Acetaminophen, 500 mg

50 Caplets – 500 mg each

PAIN RELIEF EXTRA STRENGTH

acetaminophen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-084
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	M2A4;57344
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-084-24	1 in 1 CARTON	06/13/2014	08/31/2026
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63868-084-50	1 in 1 CARTON	06/13/2014	08/31/2026
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:63868-084-10	1 in 1 CARTON	06/13/2014	08/31/2026
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:63868-084-05	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/13/2014	
5	NDC:63868-	2 in 1 CARTON	06/13/2014	04/30/2018

3	084-20	2 in 1 CARTON	06/13/2014	04/30/2018
5		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/13/2014	

Labeler - Chain Drug Marketing Association (011920774)

Revised: 10/2024 Chain Drug Marketing Association