

**PANADOL EXTRA STRENGTH- acetaminophen tablet, film coated**  
**Haleon US Holdings LLC**

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***Drug Facts***

***Active ingredient (in each caplet)***

Acetaminophen 500 mg

***Purposes***

Pain reliever/Fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - backache
  - muscular aches
  - minor arthritis pain
- temporarily reduces fever

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 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:** A-cetaminophen 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 a 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
- redness or swelling is present
- any new symptoms appear

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:**

Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. 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 of age and over: take 2 caplets every 6 hours, while symptoms persist or as directed by a doctor
- do not take more than 8 caplets in 24 hours, unless directed by a doctor
- children under 12 years of age: ask a doctor

***Other information***

- store below 25°C (77°F)

***Inactive ingredients***

carnauba wax, hypromellose, polyethylene glycol, povidone, pregelatinized starch, stearic acid

***Questions or comments?***

**1-800-455-7139**

**Principal Display Panel**

**NDC 0135-0609-01**

**PANADOL**

**EXTRA STRENGTH**

**500**

**ACETAMINOPHEN**

**Pain Reliever**

**Fever Reducer**

**24 CAPLETS**

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**Tamper-Evident Feature:** Do not use if printed bottle seal (under cap) is missing or broken.

**READ AND KEEP CARTON FOR COMPLETE INFORMATION**

Distributed by:

**GSK** Consumer Healthcare, Warren, NJ 07059

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**PANADOL EXTRA STRENGTH**

acetaminophen tablet, film coated

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0609	
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	
CARNAUBA WAX (UNII: R12CBM0EIZ)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Product Characteristics				
Color	white	Score	no score	
Shape	OVAL (Caplet)	Size	17mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0609-01	1 in 1 CARTON	03/15/2017	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0135-0609-02	1 in 1 CARTON	03/15/2017	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0135-0609-03	1 in 1 CARTON	03/15/2017	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0135-0609-04	50 in 1 CARTON	03/15/2017	
4	NDC:0135-0609-05	2 in 1 PACKET; 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	03/15/2017	
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**Labeler -** Haleon US Holdings LLC (079944263)

Revised: 2/2024

Haleon US Holdings LLC