

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

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/Fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - backache
 - 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: 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
- 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 at 25°C (77°F)
- close cap tightly after use

Inactive ingredients

castor oil, hypromellose, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions?

1-800-455-7139

Principal Display Panel

NDC 0135-7011-04

PANADOL

EXTRA STRENGTH

500

ACETAMINOPHEN

Pain Reliever

Fever Reducer

100 CAPLETS

Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

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Tamper-Evident Feature: Do not use if printed inner safety seal under cap is broken or missing.

READ AND KEEP CARTON FOR COMPLETE INFORMATION

B-0630-764-12 Front Carton



PANADOL EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-7011
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
CASTOR OIL (UNII: D5340Y2I9G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL (Caplet)	Size	17mm
Flavor		Imprint Code	PAN;ES
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-7011-03	1 in 1 CARTON	02/15/2021	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0135-7011-04	1 in 1 CARTON	03/19/2021	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0135-7011-01	2 in 1 POUCH; Type 0: Not a Combination Product	06/11/2021	
4	NDC:0135-7011-02	1 in 1 CARTON	06/08/2021	
4		24 in 1 BOTTLE; 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	02/15/2021	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 2/2024

Haleon US Holdings LLC