

**ACETAMINOPHEN AND DIPHENHYDRAMINE HCL- acetaminophen and
diphenhydramine hcl tablet
SAFEWAY**

**Extra Strength
Pain Relief PM**

Acetaminophen USP, 500mg Diphenhydramine HCL USP, 25mg

**Pain Reliever/Nighttime Sleep-Aid
Non-Habit Forming**

Active ingredients Purpose (in each caplet)

Acetaminophen USP, 500 mg

Diphenhydramine HCl USP, 25 mg

Purposes

Pain reliever

Nighttime sleep aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

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

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.
- with any other product containing diphenhydramine, even one used on skin

- in children under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

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 at bedtime
 - do not take more than 2 caplets of this product in 24 hours
- children under 12 years
- do not use

Other Information

- store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature.
- see end panel for lot number and expiration date

Inactive Ingredients

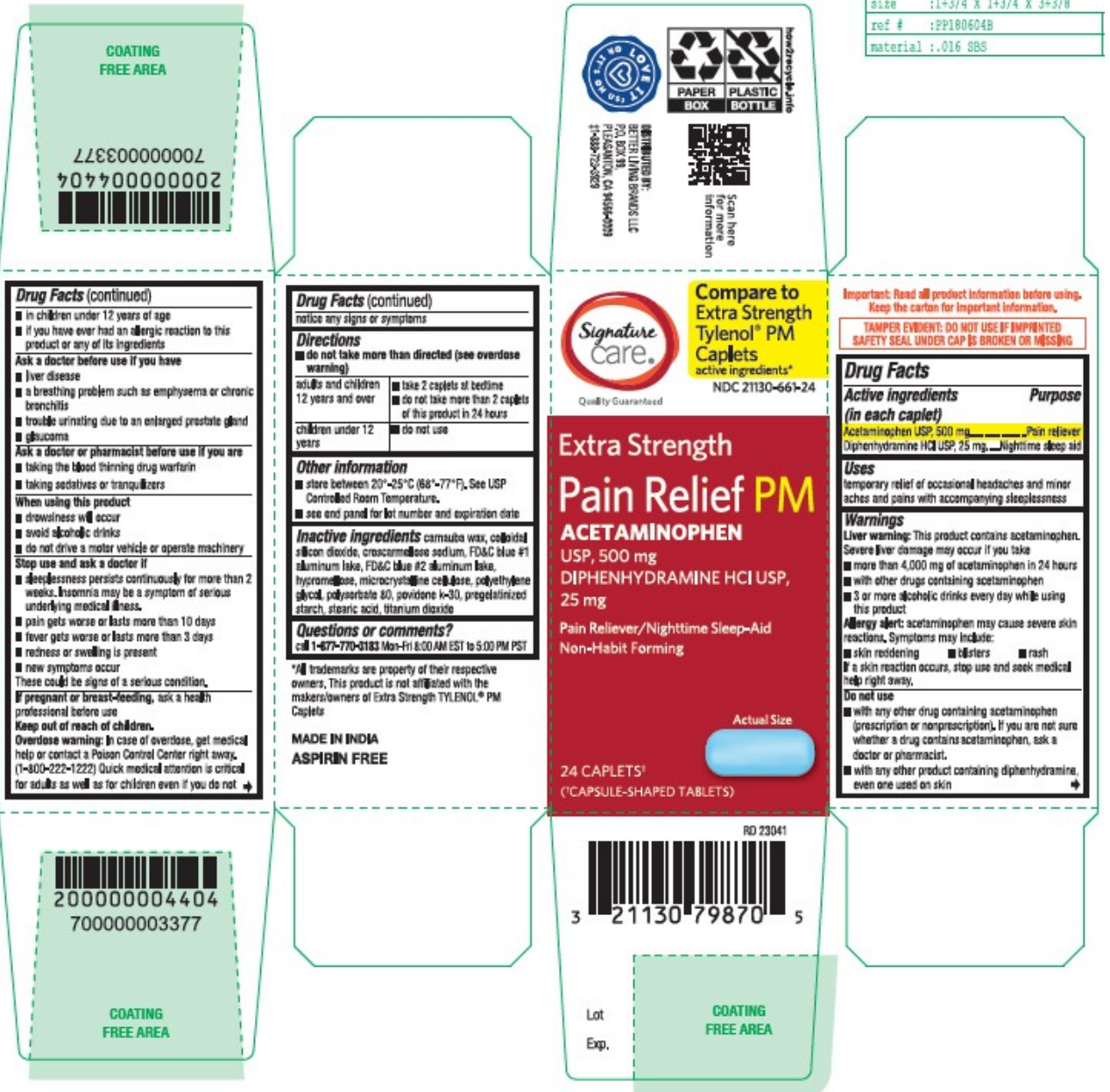
carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone k-30, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

PDP

size : 1+3/4 X 1+3/4 X 3+3/8
 ref # : PP180604B
 material : .016 SBS



ACETAMINOPHEN AND DIPHENHYDRAMINE HCL

acetaminophen and diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-661
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE (UNII: 8GTS82S83M) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE K30 (UNII: U725QWY32X)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL (caplet-shaped)	Size	17mm
Flavor		Imprint Code	G651
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-661-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2023	
2	NDC:21130-661-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2023	
3	NDC:21130-661-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/30/2023	

Labeler - SAFEWAY (009137209)