

**ACETAMINOPHEN DIPHENHYDRAMINE HCL- acetaminophen diphenhydramine
hcl tablet
BETTER LIVING BRANDS LLC.**

**Extra Strength
Pain Relief PM**

**Acetaminophen USP, 500mg
Diphenhydramine HCL USP, 25mg**

**Pain Reliever/Nighttime Sleep-Aid
RAPID RELEASE**

Active ingredient

Acetaminophen, USP 500 mg

Diphenhydramine HCl, USP 25 mg

Purpose

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 reaction. 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 the 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.

do not take more than directed (see overdose warning)

adults and children 12 years and over

■ take 2 gelcaps at bedtime

■ do not take more than 2 gelcaps 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

colloidal silicon dioxide, croscarmellose sodium, D&C red#28, D&C yellow#10, FD&C blue#1, FD&C blue #2, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, microcrystalline cellulose, n-butyl alcohol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide, triacetin

Questions or Comments?

call **1-877-770-3183**

Mon-Fri 8:00 AM EST to 5:00 PM PST.

Principal Display Panel

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

COATING
FREE AREA



IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THE CARTON FOR IMPORTANT INFORMATION. TAMPER EVIDENT. DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts

Active ingredients (in each gelcap) **Purposes**
Acetaminophen USP, 500 mg. **Pain reliever**
Diphenhydramine HCl USP, 25 mg. **Nighttime sleep aid**

Uses

Temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness.

Warnings

Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take: more than 4,000 mg of acetaminophen in 24 hours or with other drugs containing acetaminophen or more alcoholic drinks every day while using this product.

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, itching, rash, or 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 or a breathing problem such as emphysema or chronic bronchitis or trouble urinating due to an enlarged prostate gland. if you are taking a doctor or pharmacist before use if you are

Drug Facts (continued)

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 stress 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.

If pregnant or breast-feeding, ask a health professional before use. Keep out of the reach of children. Overdose warnings: 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 gelcaps at bedtime do not take more than 2 gelcaps 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 and read for expiration date and lot number.

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, D&C red # 28, D&C yellow # 10.

Drug Facts (continued)

FD&C blue # 1, FD&C blue # 2, FD&C red # 40, FD&C yellow # 6, gelatin, hydroxypropyl cellulose, hypromellose, polypropylene glycol, microcrystalline cellulose, n-butyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, stearic acid, titanium dioxide, triacetin.

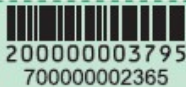
Questions or comments? call 1-877-770-5183 Mon-Fri 8:00 AM EST to 5:00 PM PST

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Extra Strength Tylenol® PM.



Compare to Extra Strength Tylenol® PM active ingredients*
NDC 21130-354-02

PMS 286 CMYK
PMS 424 CMYK



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RAPID RELEASE

Extra Strength Pain Relief PM

ACETAMINOPHEN USP, 500 mg
DIPHENHYDRAMINE HCl USP, 25 mg
Pain Reliever/Nighttime Sleep-Aid

20 GELCAPS

Actual Size

Compare to Extra Strength Tylenol® PM active ingredients*

Extra Strength Pain Relief PM

ACETAMINOPHEN USP, 500 mg
DIPHENHYDRAMINE HCl USP, 25 mg

Pain Reliever/Nighttime Sleep-Aid

RAPID RELEASE

Actual Size

20 GELCAPS

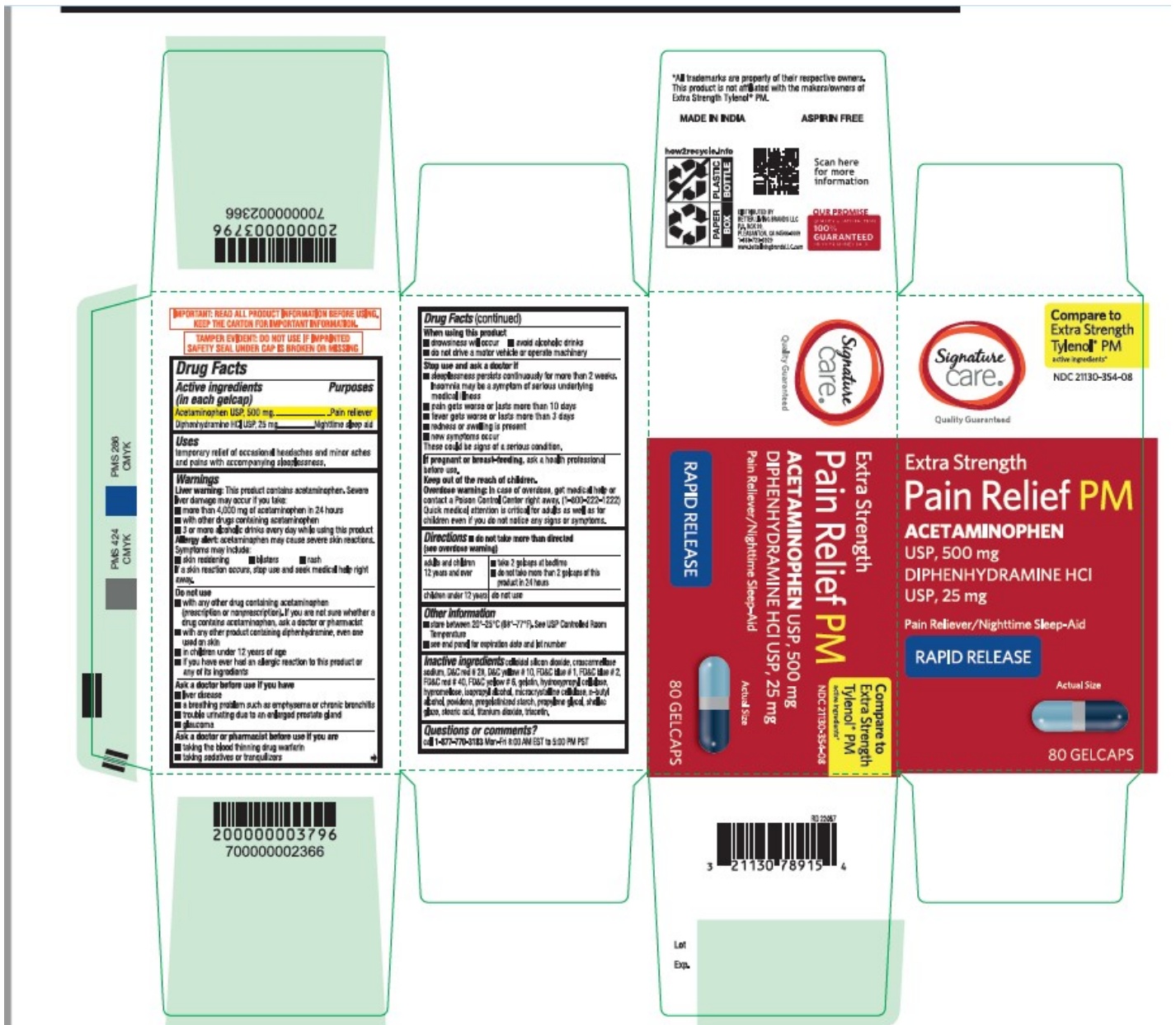


Scan here for more information
RD 32087



Lot
Exp.

COATING
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ACETAMINOPHEN DIPHENHYDRAMINE HCL

acetaminophen diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-354
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIACETIN (UNII: XHX3C3X673)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ISOPROPYL ALCOHOL (UNII: ND2M4163O2)	
POVIDONE K30 (UNII: U725QWY32X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	gray ((Encapsulated gray color tablets with dark blue opaque and light blue opaque hard gelatin shells))	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	G3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-354-02	20 in 1 BOTTLE; Type 0: Not a Combination Product	12/12/2022	
2	NDC:21130-354-08	80 in 1 BOTTLE; Type 0: Not a Combination Product	12/12/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/12/2022	

Revised: 12/2023

BETTER LIVING BRANDS LLC.