PAIN RELIEF PM - acetaminophen, diphenhydramine hcl tablet, coated
Avema Pharma Solutions

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Extra Strength Pain Relief PM

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep aid

Uses

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

Warnings

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

- more than 2 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

Do not use

- with other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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
- asthma
- breathing problems such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urinating due to an enlargement of the prostate gland

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 a serious underlying medical illness.
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- redness or swelling is present
- new symptoms occur

If pregnant or breast-feeding, ask a health care professional before use.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. 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**
- **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 this product in children under 12 years of age. This will provide more than the recommended dose (overdose) and may cause liver damage.

Other information
- store at room temperature 15°-30°C (59°-86°F), avoid high humidity and excessive heat
- do not use if imprinted safety seal under cap is broken or missing
- **This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered
  trademark Tylenol® PM

Inactive ingredients
colloidal silicon dioxide*, croscarmellose sodium*, Dand C Yellow No. 10 Aluminum Lake*, FDandC Blue No.1 Aluminum Lake, FDandC Blue No. 2 Aluminum Lake, hypromellose, magnesium silicate*, magnesium stearate*, microcrystalline cellulose, mineral oil*, polyethylene glycol, polyvinyl alcohol*, povidone, pregelatinized starch, silica*, sodium starch glycolate*, stearic acid, talc*, titanium dioxide, triacetin*, and yellow iron oxide*

*contains one or more of these ingredients

Product Labeling
**Compare to the active ingredients in Tylenol® PM®

EXTRA STRENGTH

Pain Relief PM

Acetaminophen 500 mg, Diphenhydramine HCl 25 mg

Pain reliever /
Nighttime Sleep-Aid

24 CAPLETS

Do not use if imprinted safety seal under cap is broken or missing

Drug Facts (continued)

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 this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information ■ store at room temperature 15°-30°C (59°-86°F), avoid high humidity and excessive heat ■ do not use if imprinted safety seal under cap is broken or missing ■ **This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® PM

Inactive ingredients colloidal silicon dioxide*, croscarmellose sodium*, D&C Yellow

**Compare to the active ingredients in Tylenol® PM®

NDC 63548-0065-1

Extra Strength

Pain Relief PM

Acetaminophen, 500 mg • Diphenhydramine HCl, 25 mg

Pain Reliever/ Nighttime Sleep Aid

24 CAPLETS

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 500 mg	Pain reliever
Diphenhydramine HCl 25 mg	Nighttime sleep aid

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

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 2 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

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 other products 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 a serious underlying medical illness. ■ pain gets worse or lasts for more than 10 days ■ fever gets worse or lasts for more than 3 days ■ redness or swelling is present ■ new symptoms occur

If pregnant or breast-feeding, ask a health care professional before use. **Keep out of reach of children. Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a

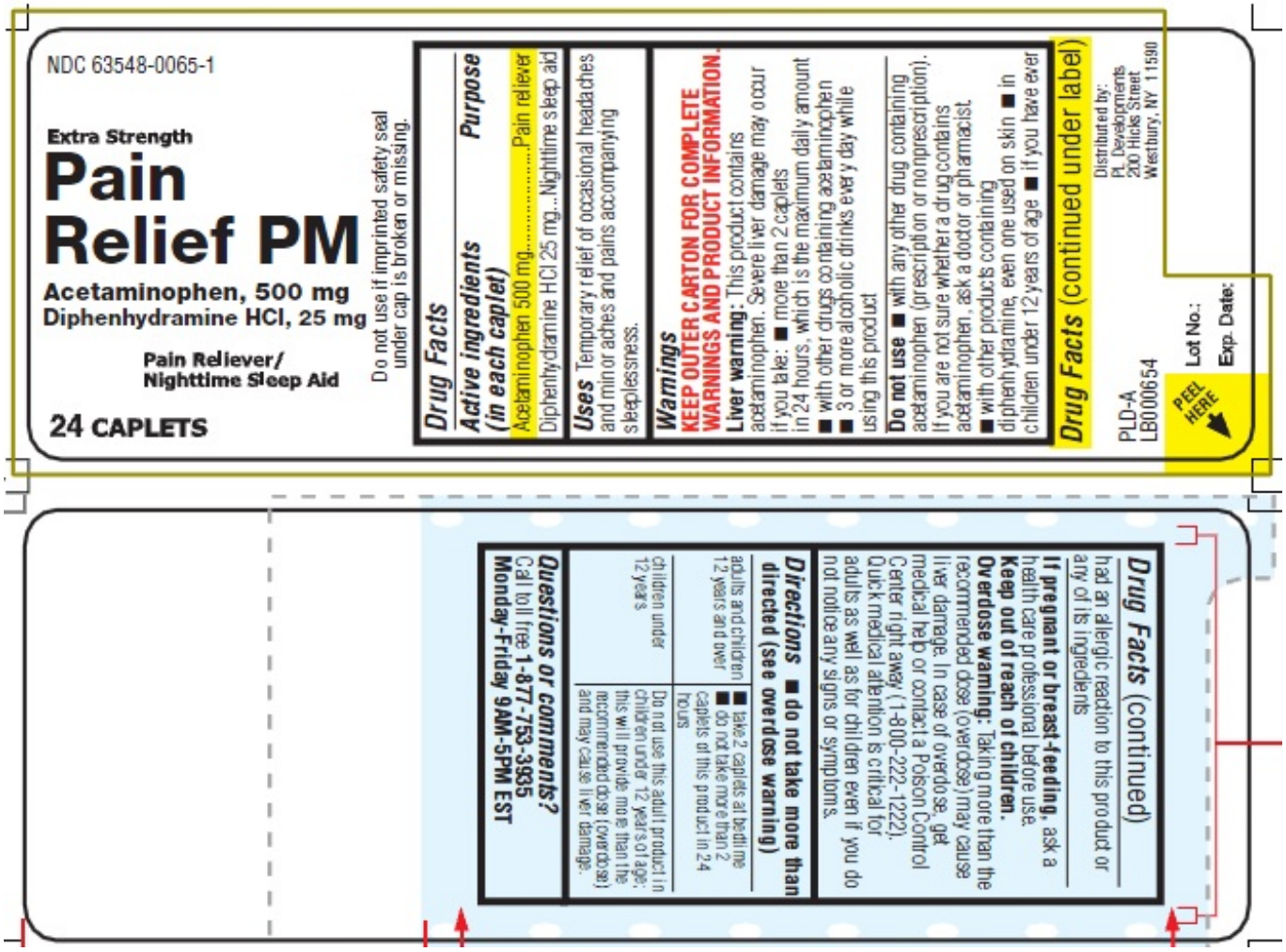
Drug Facts (continued)

#10 Aluminum Lake*, FD&C Blue #1 Aluminum Lake, FD&C Blue #2 Aluminum Lake, hypromellose, magnesium silicate*, magnesium stearate*, microcrystalline cellulose, mineral oil*, polyethylene glycol, polyvinyl alcohol*, povidone, pregelatinized starch, silica*, sodium starch glycolate*, stearic acid, talc*, titanium dioxide, triacetin*, and yellow iron oxide*

*contains one or more of these ingredients

Questions or comments?

Call toll free **1-877-753-3935**
Monday-Friday 9AM-5PM EST



PAIN RELIEF PM

acetaminophen, diphenhydramine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63548-0065
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	7mm
Flavor		**Imprint Code**	V15AV;S525;CPC752
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63548-0065-1	1 in 1 BOX		
1		24 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/14/2012	

Labeler - Avema Pharma Solutions (804087794)

Revised: 5/2012 Avema Pharma Solutions