PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen, diphenhydramine hcl tablet, coated
Walgreens

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.

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep-aid

Uses

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

Warnings

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 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 problems 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.
- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

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. 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 15-30°C (59-86°F)
- avoid high humidity and excessive heat

Inactive ingredients

carnauba wax*, croscarmellose sodium*, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate*, microcrystalline cellulose, polyethylene glycol, polysorbate 80*, polyvinyl alcohol*, povidone K30, pregelatanized starch, purified water*, silicon dioxide*, sodium starch glycolate*, stearic acid*, talc*, titanium dioxide

*contains one or more of these ingredienrts

Questions or comments?

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

Principal Display Panel

Compare to Extra Strength Tylenol® PM active ingredients††

Pain Reliever **PM**

ACETAMINOPHEN 500 mg/ PAIN RELIEVER

DIPHENHYDRAMINE HCl 25 mg/ NIGHTTIME SLEEP AID

NIGHTTIME EXTRA STRENGTH CAPLETS

CAPLETS**

(**CAPSULES-SHAPED TABLETS)

††This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol® PM.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com

Package Label

Walgreens

Pain Reliever PM

ACETAMINOPHEN 500 mg / PAIN RELIEVER
DIPHENHYDRAMINE HCl 25 mg / NIGHTTIME SLEEP AID

NIGHTTIME | EXTRA STRENGTH | CAPLETS

100 CAPLETS**
(**CAPSULE-SHAPED TABLETS)

ACTUAL SIZE

Compare to Extra Strength Tylenol® PM active ingredients††

NDC 0363-4470-10

Drug Facts

Active ingredients (in each caplet) — **Purposes**

Acetaminophen 500 mg ..... Pain reliever
Diphenhydramine HCl 25 mg ..... Nighttime sleep-aid

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

Warnings

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

Drug Facts (continued)

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
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Stop use and ask a doctor if
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- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

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 (1-800-222-1222) 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)
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Other information
- store between 15-30°C (59-86°F)
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Drug Facts (continued)

Inactive ingredients carnauba wax*, croscarmellose sodium*, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate*, microcrystalline cellulose, polyethylene glycol, polysorbate 80*, polyvinyl alcohol*, povidone K30, pregelatinized starch, purified water*, silicon dioxide*, sodium starch glycolate*, stearic acid*, talc*, titanium dioxide
*contains one or more of these ingredients

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†Walgreens Pharmacist Survey
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TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

how2recycle.info

Empty & Replaced Cap
PAPER BOX | PLASTIC BOTTLE

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015

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FC005062

ORG0718-F

Lot No.:
Exp. Date:

WALGREENS Pain Reliever PM

PAIN RELIEVER PM EXTRA STRENGTH

acetaminophen, diphenhydramine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-4470
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	S525;P525;G651
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4470-10	1 in 1 BOX	12/30/2014	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0363-4470-15	1 in 1 BOX	12/30/2014	
2		150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:0363-4470-24	1 in 1 BOX	12/30/2014	
3		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:0363-4470-11	1 in 1 BOX	12/30/2014	
4		110 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
5	NDC:0363-4470-30	1 in 1 BOX	12/30/2014	
5		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:0363-4470-52	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/30/2014	

Labeler - Walgreens (008965063)

Revised: 10/2019 Walgreens