RIGHT REMEDIES EXTRA STRENGTH PM PAIN RELIEF- acetaminophen, diphenhydramine hydrochloride tablet, film coated Strive Pharmaceuticals Inc.

RIGHT REMEDIES EXTRA STRENGTH Pain Relief PM

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg Diphenhydramine HCl 25 mg

Purposes

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 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 a 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. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see overdose warning)
- do not take more than 2 caplets in 24 hours

adults &	 take 2 caplets at
children	bedtime
12 years of	 do not take more
age and	than 2 caplets of this
over	product in 24 hours
children	do not use
under 12	
years of	
age	

Other information

- each caplet contains: sodium 3 mg (very low sodium)
- store at room temperature between 20-25°C (68-77°F).
- avoid excessive heat, cold and humidity.

Inactive ingredients

croscarmellose sodium, FD&C blue#1 aluminium lake, FD&C blue#2 aluminium lake, hypromelloses, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone K30, purified water, silicon dioxide, sodium starch glycolate, starch, talc, titanium dioxide

Questions or comments?

1-888-577-8033 Monday-Friday 8am-4pm EST

compare to active ingredients of Extra Strength TYLENOL® PM*

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING FROM BOTTLE

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division., owner of the registered trademark Tylenol® PM.

Distributed by: Strive Pharmaceuticals Inc., East Brunswick, NJ 08816

Product of India

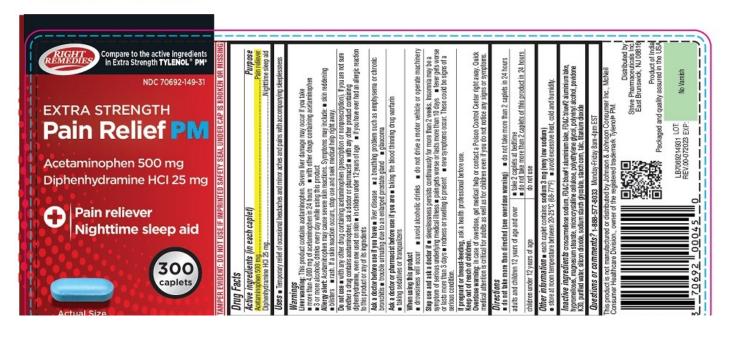
Packaged & Quality Assured in USA

CT7069214903 REV.00-082021

Packaging



PACKAGE - 300 Caplets



DRUG FACTS TABLE

Drug Facts Active ingredients (in each caplet) Purpose Pain reliever Diphenhydramine HCl 25 mg... ...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 tranqualizers

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. 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) do not take more than 2 caplets in 24 hours
- take 2 caplets at bedtime adults and children 12 years of age and over ■ do not take more than 2 caplets of this product in 24 hours children under 12 years of age do not use

Other information = each caplet contains: sodium 3 mg (very low sodium)

■ store at room temperature between 20-25°C (68-77°F)
■ avoid excessive heat, cold and humidity.

Inactive ingredients croscarmellose sodium, FD&C blue#1 aluminium lake, FD&C blue#2 aluminium lake. hypromelloses, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone K30, purified water, silicon dioxide, sodium starch glycolate, starch com, talc, titanium dioxide

Questions or comments? 1-888-577-8033 Monday-Friday 8am-4pm EST

RIGHT REMEDIES EXTRA STRENGTH PM PAIN RELIEF

acetaminophen, diphenhydramine hydrochloride tablet, film coated

Product Information

NDC:70692-149 **Product Type** HUMAN OTC DRUG Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety

l	Ingredient Name	Basis of Strength	Strength
п			

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN

500 ma

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	18mm	
Flavor		Imprint Code	S149	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692- 149-03	1 in 1 CARTON	11/13/2023	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:70692- 149-31	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/13/2023	
3	NDC:70692- 149-05	1 in 1 CARTON	11/13/2023	
3		50 in 1 BOTTLE, PLASTIC; 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	11/13/2023	

Labeler - Strive Pharmaceuticals Inc. (080028013)

Revised: 11/2023 Strive Pharmaceuticals Inc.