ACETAMINOPHEN PM- acetaminophen and diphenhydramine hydrochloride tablet, coated FSA STORE INC.

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.

1095-CRM-2023-0502

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 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 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) in a dry place
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

NDC 81522-095-03 caring mill™ †Compare to the active ingredients of Tylenol® PM Extra Strength Extra Strength Acetaminophen PM Acetaminophen, Diphenhydramine HCl Pain Reliever/Nighttime Sleep Aid For Adults Actrual Size 100 CAPLETS



ACETAMINOPHEN PM

(DIPHENHYDRAMINE - UNII:8GTS82S83M)

acetaminophen and diphenhydramine hydrochloride tablet, coated

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	Source)	NDC:8152	2-095
Route of Administration	ORAL				
Active Ingredient/Active	Molety				
Ingree	dient Name		Basis of Str	ength	Strength
ACETAMINOPHEN (UNII: 36209ITL	9D) (ACETAMINOPHEN - UNI	I:362O9ITL9D)	ACETAMINOPHEN		500 mg
DIPHENHYDRAMINE HYDROCHLO	ORIDE (UNII: TC2D6JAD40)		DIPHENHYDRAMIN	E	25 mg

25 mg

HYDROCHLORIDE

Ingredient NameStrengthSILICON DIOXIDE (UNII: ETJ7Z6XBU4)COPOVIDONE K25-31 (UNII: D9C330MD8B)CROSCARMELLOSE SODIUM (UNII: M280L1HH48)FD&C BLUE NO. 1 (UNII: H3R47K3TBD)HYPROMELLOSES (UNII: 3NXW29V3WO)LACTOSE (UNII: J2B2A4N98G)MAGNESIUM STEARATE (UNII: 70097M6I30)CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U)POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MQ0SDW1A)POVIDONE, UNSPECIFIED (UNII: R5298)GH94E)STARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)TTANUM DOWIDE (UNII: 4ELV7265AP)	Inactive Ingredients	
COPOVIDONE K25-31 (UNII: D9C330MD8B)CROSCARMELLOSE SODIUM (UNII: M280L1HH48)CROSCARMELLOSE SODIUM (UNII: M280L1HH48)FD&C BLUE NO. 1 (UNII: H3R47K3TBD)FD&CHYPROMELLOSES (UNII: 3NXW29V3WO)CROSCARMELLOSES (UNII: 3NXW29V3WO)LACTOSE (UNII: J2B2A4N98G)CROSCARMELLOSE (UNII: 70097M6I30)CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)CROSCARMELLOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MQ0SDW1A)CROSCARMELLOSEPOVIDONE, UNSPECIFIED (UNII: FZ989GH94E)STARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)CROSCARMELORSTEARIC ACID (UNII: 4ELV7Z65AP)CROSCARMELOR	Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)Image: Croscarmellose sodium (UNII: M28OL1HH48)FD&C BLUE NO. 1 (UNII: H3R47K3TBD)Image: Croscarmellose sodium (UNII: 3NXW29V3WO)LACTOSE (UNII: 3NXW29V3WO)Image: Croscarmellose sodium (UNII: 3NXW29V3WO)LACTOSE (UNII: J2B2A4N98G)Image: Croscarmellose sodium (UNII: 70097M6I30)CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)Image: Croscarmellose sodium (UNII: OP1R32D61U)POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)Image: Croscarmellose sodium (UNII: FZ989GH94E)STARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)Image: Croscarmellose sodium starch GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)STEARIC ACID (UNII: 4ELV7Z65AP)Image: Croscarmellose sodium starch GLYCZ65AP)	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)Image: Comparison of the	COPOVIDONE K25-31 (UNII: D9C330MD8B)	
HYPROMELLOSES (UNII: 3NXW29V3WO)Image: Sint Sint Sint Sint Sint Sint Sint Sint	CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
LACTOSE (UNII: J2B2A4N98G)Image: Comparison of the comparis	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)Image: Cellulose, microcrystalline (UNII: 0P1R32D61U)Polyethylene glycol, UNSPECIFIED (UNII: 3WJQ0SDW1A)Image: Cellulose, microcrystalline (UNII: 3WJQ0SDW1A)Povidone, UNSPEciFIED (UNII: FZ989GH94E)Image: Cellulose, microcrystalline (UNII: FZ989GH94E)Starch, Pregelatinized corn (UNII: 08232NY3SJ)Image: Cellulose, microcrystalline (UNII: AG9B65PV6B)Sodium starch glycolate type a corn (UNII: AG9B65PV6B)Image: Cellulose, microcrystalline (UNII: 4ELV7Z65AP)	HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)Cellulose, Microcrystalline (UNII: OP1R32D61U)POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)CellulosePOVIDONE, UNSPECIFIED (UNII: FZ989GH94E)CelluloseSTARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)CelluloseSODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)CelluloseSTEARIC ACID (UNII: 4ELV7Z65AP)Cellulose	LACTOSE (UNII: J2B2A4N98G)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)Image: Constant of the state of t	MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)STARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)STEARIC ACID (UNII: 4ELV7Z65AP)	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)STEARIC ACID (UNII: 4ELV7Z65AP)	POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) STEARIC ACID (UNII: 4ELV7Z65AP)	POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	STARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)	
	SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
	STEARIC ACID (UNII: 4ELV7Z65AP)	
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	AAA;1031
Contains			

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:81522- 095-03	1 in 1 CARTON	05/02/2023	
1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing	Information		
	Information	Maukating Chart	Mayleating Fud
Marketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - FSA STORE INC. (049283340)

Revised: 5/2023

FSA STORE INC.