PANADOL PM- acetaminophen and diphenhydramine hcl tablet, film coated
Haleon US Holdings LLC

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 are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have

- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking
- the blood thinning drug warfarin
- 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 more than 10 days
- redness or swelling is present
- any new symptoms appear

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:

Taking more than the recommended dose can cause serious health problems. 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 of age and over: take 2 caplets at bedtime, if needed, or as directed by a doctor
- do not give to children under 12 years of age

Other information (2 caplets)
- store at 25°C (77°F)

Other information (24 and 50 caplets)
- store at 25°C (77°F)
- close cap tightly after use

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, FD&C blue no. 1 aluminum lake, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions?

1-800-455-7139

Additional Information *(2 caplets)*

TAMPER-EVIDENT FEATURE: DO NOT USE IF PACKET IS DAMAGED OR OPEN

Fold Back And Tear To Open Or Use Scissors

Dist. by: **GSKConsumer Healthcare,**Warren, NJ 07059

Additional Information (*(24 and 50 caplets)*

Tamper-Evident Feature: Do not use if printed inner safety seal under cap is broken or missing.

READ AND KEEP CARTON FOR COMPLETE INFORMATION

Dist. by: **GSKConsumer Healthcare**

Warren, NJ 07059

Principal Display Panel

NDC 0135-7021-03

Panadol

EXTRA STRENGTH

PM

ACETAMNOPHEN

Pain Reliever

DIPHENHYDRAMINE HCl

Nighttime Sleep-Aid

50 CAPLETS

Tamper-Evident Feature: Do not use if printed inner safety seal under cap is broken or missing.

READ AND KEEP CARTON FOR COMPLETE INFORMATION

Dist. by: **GSKConsumer Healthcare**

Warren, NJ 07059

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B-0630-765-08 ORG

PANADOL PM

acetaminophen and diphenhydramine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0135-7021
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ACETATE (UNII: 32K497ZK2U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL (Caplet)	**Size**	17mm
Flavor		**Imprint Code**	PAN;PM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-7021-01	50 in 1 CARTON	05/19/2022	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0135-7021-02	1 in 1 CARTON	12/07/2021	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0135-7021-03	1 in 1 CARTON	12/07/2021	
3		50 in 1 BOTTLE; 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	06/25/2021	

Labeler - Haleon US Holdings LLC (079944263)