NOTTS - PAIN RELIEF PM- acetaminophen, diphenhydramine hydrochloride tablet
VIVUNT PHARMA LLC

NOTTS - Pain Relief PM

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, 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, which is the maximum daily amount.
- 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
- rash
- blisters

If a skin reaction occurs, stop use and seek medical attention immediately.

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 any other ingredient in this product.

Ask a doctor before use if you have
- liver disease

- breathing problems such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urinatation due to enlargement of the prostate gland

When using this product

avoid alcoholic drinks

Ask a doctor or pharmacist before use if you are taking

- the blood thinning drug warfarin
- sedatives or tranquilizers

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks, consult your doctor. Insomnia may be a symptom of serious underlying medical illness.
- pain lasts more than 10 days
- pain gets worse
- new symptoms occur
- redness or swelling is present.

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

Do not take more the recommended dosage. In case of overdose, get medical help or contact a Poison Control Center. Prompt 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 if needed, or as directed by a doctor. ▪ do not take more than 2 caplets in 24 hours
children under 12 years	do not use

Other information

- Store between 20-25°C (68-77°F)

- Tamper-evident: Do not use if carton is open or if the foil inner seal is broken or missing.

Inactive ingredients

Corn Starch, FD&C Blue No. 2, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Stearic Acid, Sodium Starch Glycolate, Titanium Dioxide.

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

Product of China

Distributed by:

VIVUNT PHARMA LLC

8950 SW 74th Court, Suite 1901

Miami, Florida Z.C. 33156-3175

PRINCIPAL DISPLAY PANEL - 24 Caplets

NOTTS™

Pain Relief PM

Acetaminophen,

Diphenhydramine HCl

500 mg/ 25 mg each caplet

Pain Reliever
Nighttime Sleep Aid
Non-habit Forming

Compare to Tylenol® Extra Strength PM active ingredients*

NDC 82706-009-01

24 CAPLETS

PRINCIPAL DISPLAY PANEL - 50 Caplets

NOTTS™

Pain Relief PM

Acetaminophen,

Diphenhydramine HCl

500 mg/ 25 mg each caplet

- Pain Reliever
- Nighttime Sleep Aid
- Non-habit Forming

Compare to Tylenol® Extra Strength PM active ingredients*

NDC 82706-009-02

50 CAPLETS

NOTTS - PAIN RELIEF PM

acetaminophen, diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82706-009
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
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	blue (Light Blue)	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	NOTTS;PM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-009-01	1 in 1 CARTON	08/17/2022	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:82706-009-02	1 in 1 CARTON	08/17/2022	
2		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	08/17/2022	

Labeler - VIVUNT PHARMA LLC (045829437)