ACETAMINOPHEN PM - acetaminophen, diphenhydramine hcl tablet
TDS Pharm Co., Ltd.

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 500mg

Diphenhydramine HCl 25mg

Purpose

Pain reliever

Sleep aid

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessnes

Warnings

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Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000ms of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a 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
- 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
- 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
- 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.

Enter section text here

Overdose warning:

Taking more than the recommended dose (overdose) may cause liver damage. 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 under 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 this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information
- do not use if safety seal under cap is broken or missing
- store between 20-25°C (68-77°F)
- see end panel for lot number and expiration date

Inactive ingredients

corn starch, cydroxypropyl cellulose, hypromellose 2910, blue no.1, magnesium stearate, microcrystalline cellulose, polyethylene glycol 6000, sodium starch glycolate, titanium dioxide

non-aspirin PM

ACETAMINOPHEN PM

acetaminophen, diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42912-0154
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**
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue (blue)	**Score**	no score
Shape	ROUND	**Size**	17mm
Flavor		**Imprint Code**	PM
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42912-0154-2	1 in 1 BOX		
1		24 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/28/2011	

Labeler - TDS Pharm Co., Ltd. (689951176)

Registrant - TDS Pharm Co., Ltd. (689951176)

Establishment

Name	Address	ID/FEI	Business Operations
TDS Pharm Co., Ltd.		689951176	manufacture

Revised: 1/2011 TDS Pharm Co., Ltd.