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

Enter section text here

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	do not use this adult product in children under 12 years of age; this will provide
years	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



Drug Facts (continued)

Directions ■ do not take more than directed (see overdose warning)

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

NDC No. 42912-0154-2

*Compare to the active ingredient

of Extra Strength Tylenol® PM

Active ingredients (in each caplet)
Acetaminophen 500 mg.......Pain reliever
Diphenhydramine HCl 25 mg..Nighttime sleep air Purpose

Uses temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

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 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

Drug Facts (continued)

■ 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

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Exclusively distributed b Kareway Product Inc. Compton, CA 90220 Made in Korea

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Pure-Aid™ (*Pain Relief*

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Kareway Product Inc. Compton, CA 50220 Made in Korea

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	
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	500 mg	
DIPHENHYDRAMINE HYDRO CHLO RIDE (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, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL 6000 (UNII: 30 IQX730 WE)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

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

P	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	0 1/28/20 11	

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.