ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE- acetaminophen and diphenhydramine hydrochloride tablet
Cispharma, 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.

ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE CAPLETS

Drug Facts

Active ingredient (in each caplet)

Acetaminophen .....500 mg

Diphenhydramine HCl .....25 mg

Pain Reliver

Nighttime Sleep Aid

Uses

temporarily 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 everyday 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 doctor or pharmacist. ■ with any 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.

Indicated for pain relief and night time sleep aid.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdasage Warnings;

Taking more than the recommended dose (overdose) may liver damage. In case of overdose, get medical help or contact 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 and over	• 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

- store between 20°- 25°C (68°- 77°F)
- **do not use if the box is opened**

Inactive Ingredients

Carnauba wax, FD&C blue # 1 al lake, FD&C blue # 2 al lake, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, stearic acid, titanium dioxide, triacetin

*This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, distributor of Tylenol® PM

Questions or Comments?
Call 1-866-383-9908

Manufactured by:

Cispharma Inc
1212 Cranbury S River Road
Cranbury, NJ 08512

ACETAMINOPHEN AND DIPHENHYDRAMINE HCL CAPLETS, 500 MG AND 25 MG

Pain Reliever **NDC number 52204-124-99**
Nighttime sleep aid **Contains No Aspirin**
Compare to the active ingredient in Tylenol® PM*

Drug Facts
Active ingredient (in each caplet) Purpose
Acetaminophen 500 mg..... Pain reliever
Diphenhydramine HCl 25 mg..... Nighttime sleep aid

Uses
- temporarily 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 everyday 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 doctor or pharmacist. ■ with any 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; Taking more than the recommended dose (overdose) may liver damage. In case of overdose, get medical help or contact 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.

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1212 Cranbury S River Road
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Batch: **Exp:**
Gross wt: kg Tare wt: kg Net wt: kg

Total No. of tablets:

ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE

acetaminophen and diphenhydramine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52204-124
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	BLUE (Blue)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	C;24
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52204-124-99	24390 in 1 DRUM		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/28/2011	

Labeler - Cispharma, Inc (833171445)

Registrant - Cispharma, Inc (833171445)

Establishment

Name	Address	ID/FEI	Business Operations
Cispharma, Inc		833171445	manufacture

Revised: 3/2011 Cispharma, Inc