ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE- acetaminophen and diphenhydramine hydrochloride tablet, film coated
HIMPRIT PHARMACHEM PVT 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.

ACETAINOPHEN AND DIPHENHYDRAMINE HCL TABLETS 500/25 mg

Drug Facts

Active ingredients (in each Caplet)	**Purpose**
Acetaminophen 500 mg	Pain reliever/ fever reducer
Diphenhydramine HCL 25 mg	Sleep Aid

Uses

Temporary relief of occasional headaches and minor aches and pain with accompanying sleeplessness

Warnings

Alcohol Warnings

If you consume 3 or more alcoholic drinks every day, ask your doctor if you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Do not use

* with any other product containing acetaminophen
* with any other product containing diphenhydramine, even one used on skin
* in children under 12 years of age

Ask a doctor before use if you have

* a breathing problem such as emphysema or chronic bronchitis
* glaucoma
* difficulty in urination due to enlargement of the prostate gland

ASK a doctor or pharmacists before use if you are taking sedatives or tranquilizers

When using this product

* do not exceed recommended dosage
* avoid alcoholic beverages
* marked drowsiness may occur
* do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

* sleeplessness persists continuously for more than two weeks. Insomnia may be a symptom of a serious underlying medical illness
* new symptoms occur

* redness or swelling is present
* pain gets worse or lasts more than 10 days
* fever gets worse or lasts more than 3 days

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

Keep out of reach of children. In case of accidental overdose get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Direction

* use as directed
* adults and children 12 years and over : take 2 caplets at bedtime or as directed by a doctor
* 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 could cause serious health problems.

Other information

* Store at room temperature

Inactive ingredients

croscarmellose sodium, hypromellose, polythlene glycol,sodium metabisulfate, stearic acid,, sodium starch glycolate,collodial silicon dioxide, FD & C blue # 1

PRINCIPAL DISPLAY PANEL 500/25 mg Shipper Label

ACETAMINOPHEN AND DIPHENHYDRAMINE HCL TABLETS
Each Film coated Tablet Contains:
ACETAMEINOPHEN 500 mg
DIPHENHYDRAMINE HCL 25 mg

Lot No :
MFG. DATE :
Exp. Date :
Jar No. :
Quantity : 31000 Tablets
NDC. No : 65437-041-31

WARNING :
KEEP OUT OF THE REACH OF CHILDREN

STORE CONTROLLED ROOM TEMPRATURE OF 59° –86°F (15° – 30°C)
PROTECT FROM LIGHT, MOISTURE AND FREEZING

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.
CONTENTS SHOULD BE APPROVED,REPACKAGED IMMEDIATELY AND LABELED IN STRICT
CONFORMANCE WITH THE FDA AND REGULATIONS THEREUNDER

MANUFACTURED BY:
MANUFACTURED CODE No Guj/Drugs/G/1362
LABELER CODE # 14803

MANUFACTURED FOR:
HIMPRIT PHARMACHEM PVT. LTD
"LAKULISH", R.V.DESAI ROAD,
NEXT TO NAVAPURA POLICE STATION
BARODA, INDIA – 390 001

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"

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ACETAMINOPHEN AND DIPHENHYDRAMINE HYDROCHLORIDE

acetaminophen and diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65437-041
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
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	OVAL (Capsule Shaped)	**Size**	18mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65437-041-31	1 in 1 DRUM		
1		31000 in 1 BAG		
2	NDC:65437-041-50	1 in 1 DRUM		
2		50000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/01/2010	

Labeler - HIMPRIT PHARMACHEM PVT LTD (917261992)

Revised: 6/2010 HIMPRIT PHARMACHEM PVT LTD