ACETAMINOPHEN- acetaminophen 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 TABLETS USP 500 mg

Drug Facts

Active ingredients (in each Caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/ fever reducer

Uses

Temporarily relieves minor aches and pains due to :

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* headache
* backache
* the common cold
* menstrual cramps
* muscular aches
* arthritis
* toothache
* reduces fever

Warnings

Overdose Warning

Taking more than the recommended dose can cause serious health problems, including 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 you do not notice any signs or symptoms.

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

Stop use and Ask a doctor if

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

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

Keep out of reach of children.

Direction

* do not use more that directed (see overdose warning)
* adults and children 12 years and over : take 2 caplets every 6 hours as needed
* do not take more than 8 caplets in 24 hours
* Children under 12 years : do not use this adult Extra Strength 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

PRINCIPAL DISPLAY PANEL - 500 mg Tablet Shipper Label

ACETAMINOPHEN TABLETS USP 500 mg
Each Film coated Tablet Contains:
ACETAMINOPHEN 500 MG

Lot No :
MFG. DATE :
Exp. Date :
Jar No. :
Quantity : 31000 Tablets
NDC. No : 65437-040-31

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"

ACETAMINOPHEN TABLETS USP 500 mg

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ACETAMINOPHEN

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65437-040
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	S;500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65437-040-31	1 in 1 DRUM		
1		31000 in 1 BAG		
2	NDC:65437-040-50	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 FINAL	part343	07/01/2010	

Labeler - HIMPRIT PHARMACHEM PVT LTD (917261992)

Revised: 7/2010 HIMPRIT PHARMACHEM PVT LTD