ACETAMINOPHEN- acetaminophen 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 CAPLETS, 500 mg

Drug Facts

Active ingredient (in each caplet)

Acetaminophen .....500 mg

Pain Reliever/ Fever Reducer

Uses

Temporarily relieves minor aches and pains due to:

- headache
- the common cold
- backache
- muscular aches
- minor pain of arthritis
- toothache
- premenstrual and menstrual cramps

temporarily reduces fever

Warnings

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

Do not use with any other drug containing acetaminophen

Stop use and ask a doctor if

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

These could be signs of a serious condition.

Indicated for pain relief.

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 can cause serious health problems, including 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	• take 2 caplets every 6 hours as needed. • do not take more than 8 caplets in 24 hours • do not use more than 10 days unless 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 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, hypromellose, polyethylene glycol, propylene glycol, povidone, pregelatinized starch, stearic acid, titanium dioxide

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

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

Manufactured by:

Cispharma Inc
1212 Cranbury S River Road
Cranbury, NJ 08512

ACETAMINOPHEN CAPLETS, 500 MG

Pain Reliever **NDC number 52204-115-99**
Fever Reducer **Contains No Aspirin**
Compare to the active ingredient in Tylenol®*

Drug Facts
Active ingredient (in each caplet) Purpose
Acetaminophen 500 mg..... Pain reliever/ fever reducer

Uses
- temporarily relieves minor aches and pains due to:
  - headache
  - the common cold
  - backache
  - premenstrual and menstrual cramps
  - muscular aches
  - minor pain of arthritis
  - toothache
- temporarily reduces fever

Warnings
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help or contact poison control center right away. Quick medical attention is
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Acetaminophen may cause liver damage.
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Batch: **Exp:**
Gross wt: kg Tare wt: kg Net wt: kg

Total No. of tablets:

ACETAMINOPHEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52204-115
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	C;15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52204-115-99	26549 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: 4/2011 Cispharma, Inc