

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 TABLETS, 325mg

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325 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 (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) 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 | <ul style="list-style-type: none">• take 2 tablets every 4 to 6 hours while symptoms last• do not take more than 12 tablets in 24 hours• do not use more than 10 days unless directed by a doctor |
| children 6 years to 11 years | <ul style="list-style-type: none">• take 1 tablet every 4 to 6 hours while symptoms last• do not take more than 5 tablets in 24 hours |
| children under 6 years | <ul style="list-style-type: none">• do not use adult Regular Strength product in children under 6 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 carton is opened**

Inactive Ingredients

povidone, pregelatinized starch, stearic acid

Questions or Comments?

Call 1-866-383-9908

Manufactured by:

**Cispharma Inc
1212 Cranbury S River Road
Cranbury, NJ 08512**



ACETAMINOPHEN TABLETS, 325 MG

**Pain Reliever
Fever Reducer**

NDC number 52204-113-99

Contains No Aspirin

Drug Facts

Active ingredient (in each tablet) Purpose
Acetaminophen 325 mg..... Pain reliever/ fever reducer

Uses

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

Warnings

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Do not use with any other drug containing acetaminophen

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- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

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1212 Cranbury S River Road
Cranbury, NJ 08512

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:52204-113
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE (White)	Score	2 pieces
Shape	ROUND (round)	Size	10mm
Flavor		Imprint Code	MLX;123
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52204-113-99	43956 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