

ASPIRIN- aspirin tablet, coated
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.

ASPIRIN ENTERIC COATED ORANGE TABLETS, 325 mg

Drug Facts

Active ingredient (in each tablet)

Aspirin (NSAID*) 325 mg

Pain Reliever

Uses

For the temporary relief of minor aches and pains due to headache, minor arthritis, colds, muscle pain, toothache, menstrual pain, **or as recommended by your doctor**

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- facial swelling
- asthma (wheezing)
- shock
- hives

Alcohol Warning: if you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

Do not use if you have ever had an allergic reaction to any other pain relievers/fever reducers.

Ask a doctor before use if you have

- stomach problems (such as heartburn, upset stomach, or stomach pain) that last or come back or allergic reaction to aspirin
- bleeding problems
- ulcers
- asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for

- diabetes
- gout
- arthritis
- anticoagulation (thinning of blood)

Indicated for pain relief.

Stop use and ask a doctor if

- An allergic reaction occurs. Seek medical help right away
- Pain gets worse or lasts more than 10 days
- Redness or swelling is present
- New symptoms occur
- Ringing in the ears or loss of hearing occurs.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions:

- Do not take more than directed
- Adults and children 12 years of age and over: take 1 to 2 tablets every 4 while symptoms persist. Drink a full glass of water with each dose. Do not take more than 12 tablets in 24 hours unless directed by a doctor
- Children under 12 years: consult a doctor

Other Information

- Store below 25°C

Inactive Ingredients

colloidal silicon dioxide, FD&C Yellow # 6 lake, hypromellose, methacrylic acid copolymer, starch, talc, titanium dioxide, triacetin, triethyl citrate

Questions or Comments?

Call 1-866-383-9908

Manufactured by:

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



ASPIRIN ENTERIC COATED ORANGE TABLETS, 325 MG

Pain Reliever

NDC number 52204-111-99

Regular Strength

Safety Coated

Compare to active ingredient in Ecotrin® 325 mg

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Drug Facts (continued)

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Manufactured by:

Cispharma Inc
1212 Cranbury S River Road
Cranbury, NJ 08512

Batch No.:

Exp:

Gross wt:

Tare wt:

Net wt:

No. of Tablets:

ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52204-111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	ORANGE (ORANGE)	Score	no score
Shape	ROUND (Round)	Size	11mm
Flavor		Imprint Code	C;11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52204-111-99	41026 in 1 DRUM		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	11/15/2010	

Labeler - Cispharma, Inc (833171445)

Registrant - Cispharma, Inc (833171445)

Establishment

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