

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 YELLOW TABLETS, 81 mg

Drug Facts

Active ingredient (in each tablet)

Aspirin (NSAID*) 81 mg

*Nonsteroidal anti-inflammatory drug

Pain Reliever

Uses

For the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed release action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.

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
- 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:

- drink a full glass of water with each dose.
- adults and children 12 years of age and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by doctor.
- Children under 12 years: consult a doctor

Other Information

- Store at room temperature

Inactive Ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C Yellow # 10 al lake, FD&C Yellow # 6 al lake, methacrylic acid copolymer, microcrystalline cellulose, stearic acid, talc, titanium dioxide, 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 YELLOW TABLETS, 81 MG

Pain Reliever

NDC number 52204-103-99

Low Dose

Safety Coated

Compare to active ingredient in BAYER® Low Dose

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Drug Facts (continued)

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Manufactured by:

Cispharma Inc
1212 Cranbury S River Road
Cranbury, NJ 08512

Batch:

Exp:

Gross wt: kg Tare wt: kg Net wt: kg

No. of Tablets:

ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52204-103
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)

MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)

STEARIC ACID (UNII: 4ELV7Z65AP)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics

Color	YELLOW (YELLOW)	Score	no score
Shape	ROUND (Round)	Size	6mm
Flavor		Imprint Code	C;3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52204-103-99	166667 in 1 DRUM		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	02/14/2011	

Labeler - Cispharma, Inc (833171445)

Registrant - Cispharma, Inc (833171445)

Establishment

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

Revised: 4/2011

Cispharma, Inc