

ASPIRIN- aspirin tablet, film coated
Sina Health 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.

Drug Facts

Active ingredient (in each tablet)

Aspirin (NSAID*) 325 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves minor aches and pains associated with

- headache
- minor arthritis pain
- common cold
- menstrual cramps
- muscular aches
- backache
- toothache

Temporarily reduces fever.

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:

- hives
- skin reddening
- facial swelling
- rash
- asthma (wheezing)
- blisters
- shock

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems

- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcohol drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you have ever had an allergic reaction to any other pain reliever/ fever reducer
- right before or after heart surgery
- if you are taking prescription drugs for gout, diabetes or arthritis

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- if ringing in the ears or loss of hearing occurs
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the 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 right away.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- drink a full glass of water with each dose

Adults and children: Take 1 or 2 tablets with water every 4 hours as needed. Do not

(12 years and older) take more than 12 tablets in 24 hours, or as directed by a doctor.

Children under 12 years: Do not give to children under 12 years of age.

Other information

- read all product information before using
- store at room temperature 59°-86°F (15°-30°C)
- avoid excessive heat and humidity
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

Questions or comments? 1-800-472-4346



Repackaged by
Sina Health Inc
Scottsdale, AZ 85269
Phone: 877-748-2227



NDC 70385-2005-2

Aspirin 325mg Tablets 2/Pack

Pain Reliever/Fever Reducer (NSAID) Qty: 2

OTC Lot # XXXXX Exp Date: XX/XXXX

Store at 68-77F (20-25C)
See product insert for complete use and cautionary information

Mfr by Henry Scien Inc, Melville, NY 11747 Mfr NDC: 0404-0712-13

ASPIRIN

aspirin tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70385-2005(NDC:0404-0712)
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MINERAL OIL (UNII: T5L8T28FGP)	

STARCH, CORN (UNII: O8232NY3SJ)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

Product Characteristics

Color	white (white)	Score	no score
Shape	ROUND (ROUND)	Size	10 mm
Flavor		Imprint Code	TCL;011
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70385-2005-2	2 in 1 BAG	07/03/2017	
1		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	07/25/2011	

Labeler - Sina Health Inc (047161553)

Establishment

Name	Address	ID/FEI	Business Operations
Sina Health Inc		047161553	repack(70385-2005)

Revised: 2/2019

Sina Health Inc