

ASPIRIN- aspirin tablet
Genuine First Aid LLC

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 325mg

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 ; muscular aches ; minor arthritis pain ; backache ; common cold ; toothache ; menstrual cramps
; 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 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 thinner (anticoagulant) or steroid drug; take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others); have 3 or more alcoholic 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 a prescription drug 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

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

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 areas; any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important 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 use more than directed

the smallest effective dose should be used

drink a full glass of water with each dose

do not take longer than 10 days, unless directed by a doctor

Adults and children: (12 years and older) Take 1 or 2 tablets with water every 4 hours as needed. Do not 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.

Store at 59 - 86 degree Fahrenheit (15 - 30 degree Celsius); avoid excessive heat and humidity; tamper evident sealed packets;

Do not use any opened or torn packets

Inactive Ingredients

hypromellose, polyethylene glycol, propylene glycol, corn starch

Distributed by GENUINE FIRST AID

600 Cleveland Str Suite 400, Clearwater, FL 33755

ASPIRIN

2 Tablets

Active ingredient (in each tablet) *Purpose*
Aspirin (NSAID*) 325 mg Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses Temporarily relieves minor aches and pains associated with
■ headache ■ muscular aches ■ minor arthritis pain ■ backache
■ common cold ■ toothache ■ menstrual cramps
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 thinner (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic 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 a prescription drug 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

Warnings (continued)

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 use more than directed
■ the smallest effective dose should be used
■ drink a full glass of water with each dose
■ do not take longer than 10 days, unless directed by a doctor

Adults and children: (12 years and older) Take 1 or 2 tablets with water every 4 hours as needed. Do not 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 ■ store at 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 hypromellose, polyethylene glycol, propylene glycol, corn starch

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ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52124-0011
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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white (White)	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	44;157;ASPIRIN
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52124-0011-1	2 in 1 PACKAGE; Type 0: Not a Combination Product	04/23/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	04/23/2010	

Labeler - Genuine First Aid LLC (619609857)

Revised: 12/2017

Genuine First Aid LLC