ENTERIC COATED ASPIRIN REGULAR STRENGTH- aspirin tablet, delayed release Safeway

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.

SIG - 1081B - 2019-1007

Drug Facts

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID ¹)

1 nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- for the temporary relief of minor aches and pains due to:
 - headache
 - muscle pain
 - toothache
 - o menstrual pain
 - colds
 - minor pain of arthritis
- 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:

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

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 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

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 taking a prescription drug for:

- diabetes
- gout
- arthritis

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - $\circ \;\;$ have stomach pain that does not get better
- pain gets worse or lasts for more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious condition

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 (1-800-222-1222).

Directions

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 to 2 tablets every 4 hours; do not exceed 12 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- store between 20°-25°C (68°-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

corn starch, croscarmellose sodium, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

PRINCIPAL DISPLAY PANEL

COMPARE TO

Ecotrin® Regular Strength Aspirin

Active ingredient†

NDC 21130-081-05

Signature CareTM

Quality Guaranteed

Regular Strength

Enteric Coated

Aspirin Tablets

325mg

Pain Reliever (NSAID)*

Safety Coated

500 Enteric Coated Tablets



Aspirin 325 mg (NSAID*)	Active ingredient (in each tablet)	Purpose
* non-steroidal	spirin 325 mg (NSAID*) non-steroidal anti-inflammatory drug	Pain reliever
Uses = for = muscle pain = or as recomme	the temporary relief of minor aches and pains due to: It toothache It menstrual pain It colds Inded by your doctor	headacheminor pain of arthritis
Warnings Reye's syndror flu-like symptor with nausea and	Warnings West symbol and the state of a recovering from chicken pox or of release symbol and role use this product. When using this product, if changes in behavior with neuses and vomiting occur, consult a doctor because these symptoms could be an early sign.	chicken pox or anges in behavior could be an early sign
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Do not use if you have ever Ask a doctor before use if	reaction to any other pa	r/fever reducer
 stomach blee you have a his you have high Ask a doctor on diabetes 	as stornach beleding varining applies to you are taking as stornach beleding varining applies to you have a tistory of stornach problems, such as hearthurn groun have a sistory of stornach problems, and the sease. Inter cirrhosis, or kidney disease allow the wing the blood pressure, heart disease, liver cirrhosis, or kidney disease allow the paramatist before use if you are taking a prescription drug for diabetes ground the problems.	 you are taking a diuretic you have asthma dney disease ription drug for:
Stop use and ask a doctor if you experience any of the fol have bloody or black stools pain gets worse or lasts for r riging in the ears or loss of These could be signs of a serior	Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away. you experience any of the following gains of stomach bleeding. If elect laint a wonth blood before you black stools a lave stomach pain that does not get better pain gets worse or lasts for more than 10 days a redness or swelling is present a high if the ears of ross of hearing occurs a new symptoms occur These could be stons of a serious condition.	Il help right away. It ■ vomit blood ter s present
If pregnant or not to use aspir doctor because Keep out of rea	n professional before use. If pregnancy unless definite e unborn child or complica overdose, get medical help	It is especially important ely directed to do so by a titions during delivery.
Directions and children 12 12 tablets in 24 hours 12 tablets in 24 hours 12 tablets in 29 hours	Directions ■ ethink a full glass of water with each dose builden 12 years and over: take 1 to 2 tablets every 4 hours; do not exceed 12 tablets in 24 hours; do not exceed ethidren under 12 years: ask a doctor ethidren under 12 years: ask a doctor	o not exceed
Other information	mation store between 20°-25°C (68°-77°F) in a dry place	ry place
Inactive in #6, hypromellos 80, simethicone	Inactive ingredients com starch, croscarmelices sodium, D&C yellow #10, FD&C yellow #10, FD&C yellow #10, PD&C yellow #10, PD&C yellow #10, promellose, methacryfic acid copolymer, microcrystalline celluices, mineral oil, polysoribate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate	low #10, FD&C yellow neral oil, polysorbate de, triethyl citrate
	DISTRIBUTED BY BETTER LIVING BRANDS LLC Geocommisme, destrouved or destrouted by PLEASANTON, CA, 94566-0009 WARNET STS, 3829 WARNET S	or distributed by or distributed by Ordina Regular Strength Asp

ENTERIC COATED ASPIRIN REGULAR STRENGTH

aspirin tablet, delayed release

Item Code (Source)	NDC 24422 004
nem coue (source)	NDC:21130-081

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

Inactive Ingredients		
Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
MINERAL OIL (UNII: T5L8T28FGP)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		

Product Characteristics				
Color	orange	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	T	
Contains				

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:21130-081-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/05/2015	

Labeler - Safeway (009137209)

Revised: 10/2019 Safeway