ASPIRIN LOW DOSE- as pirin tablet, delayed release WinCo Foods, 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.

WNC - 1080 - 2019-1003

Drug Facts

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID)*

* nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

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

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
- asthma (wheezing)
- shock

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 alcoholic drinks every day while using this product

• take more or for a longer time than directed

Do not use if you are allergic to aspirin or 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
 - 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 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

Other information

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

Inactive ingredients

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, starch, talc, titanium dioxide, triethyl citrate

PRINCIPAL DISPLAY PANEL

WinCoTM Foods

**Compare to the active ingredient in BAYER® Low Dose Aspirin

Low Dose

Aspirin

Relieves: Minor Aches & Pains

Aspirin (NSAID) Tablets

81 mg / Pain Reliever

120 Enteric Coated Tablets

81 mg EACH



Purpose

DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSIN

WF1810

F1080B01WNC R0

 have 3 or more alcoholic drinks every day take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, Drug Facts (continued)

while using this product

naproxen, or others)

take more or for a longer time than directed

unborn child or complications during delivery.

Keep out of reach of children. In case of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the professional before use. It is especially important not to use aspirin during the last 3 months of

Control Center right away (1-800-222-1222) overdose, get medical help or contact a Poison

Directions

Uses for the temporary relief of minor aches and pains or as recommended by your doctor.

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are age 60 or older The chance is higher if you:

- asthma (wheezing) shock
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steroid drug

take a blood thinning (anticoagulant) or

have had stomach ulcers or bleeding problems

an allergic reaction occurs. Seek medical help Stop use and ask a doctor if ■ diabetes ■ gout ■ arthritis

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Warnings

ask your doctor about other uses for this product other symptoms needing immediate relief. Because of its delayed action, this product will not provide fast relief of headaches or

Do not use if you are allergic to aspirin or any other pain reliever/fever reducer

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■ you are taking a diuretic ■ you have asthma taking a prescription drug for: Ask a doctor or pharmacist before use if you are

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 retain carton for complete product information children under 12 years: consult a doctor store between 20°-25°C (68°-77°F) in a dry place Other information

> **Compare to the active ingredient in BAYER® Low Dose Aspirin Relieves: Minor Aches & Pains

If pregnant or breast-feeding, ask a health Drug Facts (continued)

81 mg EACH

EXPIRATION STAMPING FOR LOT AND

INK AND COATING FREE

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

"This product is not manufactured or distributed by BAYER

HEALTHCARE LLC, distributor of BAYER® Low Dose Aspirin.

GUARANTEE

SATISFACTION

Comments & Questions? 800-824-1706 · www.wincofoods.com

WinCo Enteric Coated Tablets ASPIRIN (NSAID) TABLETS 81 mg/PAIN RELIEVER

ASPIRIN LOW DOSE

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-123
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	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
BROWN IRON OXIDE (UNII: 1N032N7MFO)		
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
STARCH, CORN (UNII: O8232NY3SJ)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		

Product Characteristics			
Color	ye llo w	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	heart
Contains			

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-123- 12	1 in 1 CARTON	12/15/2014	
1		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/15/20 14	

Labeler - WinCo Foods, LLC (056098817)

Revised: 10/2019 WinCo Foods, LLC