

ASPIRIN LOW DOSE SAFETY COATED- aspirin tablet, coated

Freds 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 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 safety coated 81 mg aspirin

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 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 have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- gout
- diabetes
- arthritis

Stop use and ask a doctor if

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

- 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: do not use

Other information

- store at controlled room temperature 15°-30°C (59°-86°F)

Inactive ingredients

anhydrous lactose**, black iron oxide**, brown iron oxide**, croscarmellose sodium**, D&C yellow #10, FD&C yellow #6**, hypromellose**, methacrylic acid copolymer, microcrystalline cellulose, mineral oil**, polysorbate 80**, potassium hydroxide**, pregelatinized starch**, propylene glycol**, purified water**, shellac**, silicon dioxide, simethicone**, sodium bicarbonate**, sodium hydroxide**, sodium lauryl sulfate**, stearic acid**, talc, titanium dioxide, triethyl citrate, yellow iron oxide**

**contains one or more of these ingredients

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENT IN BAYER® LOW DOSE ASPIRIN†

LOW DOSE SAFETY COATED

ASPIRIN 81 mg

‡ASPIRIN REGIMEN

Pain Reliever (NSAID)

Easy Open Cap

ENTERIC COATED TABLETS

†This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose Aspirin.

‡Aspirin is not appropriate for everyone, so be sure you talk to your doctor before you begin an aspirin regimen.

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING.**

Product Label

fred's®
NDC 55315-227-03

Actual Size
Aspirin 81 mg
 Pain Reliever (NSAID)
 Easy Open Cap

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

300 Enteric Coated Tablets

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

fred's LAB TESTED
 Let's Prove It. Bring Your Aspirin For Satisfaction.

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Drug Facts (continued under label)

DISTRIBUTED BY: fred's, Inc.
 4300 NEW GETWELL RD, MEMPHIS, TN 38118
 www.fredsinc.com

fred's Promise
 Not Happy With This Product?
 Just Bring It Back For a Refund!

PLD-B LB000994 Lot No.: Exp. Date:
 0 84579 12234 9

PEEL HERE

Drug Facts (continued)

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Low Dose safety coated Aspirin 81 mg tablets

ASPIRIN LOW DOSE SAFETY COATED

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-227
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
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	E;T81;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-227-03	300 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	03/08/2013	

Labeler - Freds Inc (005866116)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 4/2013

Freds Inc