

ASPIRIN ENTERIC SAFETY COATED- aspirin tablet
Publix Supermarkets, Inc.

Aspirin 81mg Enteric Coated TCB

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 a 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
- shock
- facial swelling
- 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 longer time than directed

For external use only

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have 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

- gout
- diabetes
- arthritis

When using this product

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 more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- ringing in the ears or loss of hearing occurs
- new symptoms occur

These could be a signs of a serious condition.

Pregnancy/Breast-feeding,

ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in 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 pr contact a Poison Control Center (1-800-222-

1222) right away.

Directions

- drink a full glass of water 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 15-30°C (59-86°F)

Storage

Inactive ingredients

Croscarmellose sodium, D&C yellow #10, lactose monohydrate, methacrylic acid, microcrystalline cellulose 102, polacrillin potassium, polyethylene glycol 6000, polyvinyl alcohol, purified talc, silicon dioxide, sodium lauryl sulphate, soybean, titanium dioxide, triethyl citrate

Questions

Principal Display Panel

Compare to the active ingredient in Bayer® Low Dose Aspirin†

LOW DOSE

aspirin

ASPIRIN REGIMEN 81 mg±

PAIN RELIEVER (NSAID)

- Safety coated±±

TABLETS

†This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer® Low Dose Aspirin.

±Talk to your doctor or other healthcare provider before using this product for your health. Aspirin is not right for everyone.

±±Coating helps protect against stomach upset.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY PUBLIX SUPERMARKETS, INC.,
3300 PUBLIX CORPORATE PARKWAY,
LAKELAND, FL 33811

Package label

Drug Facts (continued)

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[†]This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer® Low Dose Aspirin.

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LOW DOSE

aspirin

ASPIRIN REGIMEN 81 mg[†]

PAIN RELIEVER (NSAID)

- Safety coated^{‡‡}

120 TABLETS

NDC 56062-063-12



ACTUAL SIZE

Compare to the active ingredient in Bayer® Low Dose Aspirin[†]

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Lot No.:

Exp. Date:

Drug Facts

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*nonsteroidal anti-inflammatory drug

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PUBLIX Low Dose Aspirin

ASPIRIN ENTERIC SAFETY COATED

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-063
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SOYBEAN (UNII: L7HT8F1ZOD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	P
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-063-12	1 in 1 BOX	07/31/2023	
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 Drug	M013	07/31/2023	

Labeler - Publix Supermarkets, Inc. (006922009)

Registrant - P & L Development, LLC (079765031)

Revised: 11/2024

Publix Supermarkets, Inc.