ASPIRIN- aspirin tablet, coated PUBLIX SUPER MARKETS INC

PBX-1018-2020-0820

Drug Facts

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID) *

* nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves:

- headache
- muscle pain
- toothache
- menstrual pain
- pain and fever of colds
- minor pain of arthritis

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
- fever gets worse or lasts for more than 3 days
- 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 or 2 tablets every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours

• 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

corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 56062-118-11

REGULAR STRENGTH

aspirin

325 mg

PAIN RELIEVER/ FEVER REDUCER (NSAID)

ACTUAL SIZE

100 COATED TABLETS

†Compare to the active ingredient in Genuine Bayer® Aspirin



ASPIRIN

aspirin tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-118	
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	TCL;011	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:56062- 118-11	1 in 1 CARTON	05/01/2020		
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:56062- 118-15	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020	11/30/2022	
3	NDC:56062- 118-17	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	05/01/2020		

Labeler - PUBLIX SUPER MARKETS INC (006922009)

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