# ASPIRIN LOW DOSE SAFETY COATED- as pirin tablet P and L Development of New York Corporation

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.

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#### **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 experienece any of the following signs of stomach bleeding:
  - feel faint
  - have bloody or black stools
  - o vomit blood
  - have stomach pain that does not get better
- 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\*\*

<sup>\*\*</sup>contains one or more of these ingredients

#### Questions or comments?

Call toll free 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

Pain Reliever (NSAID)

‡Aspirin Regimen

#### **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.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

#### **Product Label**



# ASPIRIN LOW DOSE SAFETY COATED aspirin tablet

# Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:59726-227 Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

ASPIRIN (ASPIRIN)	ASPIRIN	81 mg
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Ingredient Name COLYSORBATE 80 COLYS	Inactive Ingredients			
DIMETHICONE  GO DIUM HYDRO XIDE  GO DIUM LAURYL SULFATE  FALC  FRIETHYL CITRATE  ANHYDRO US LACTOSE  FERROSO FERRIC O XIDE  BRO WN IRON O XIDE  CROSCARMELLOSE SODIUM  DAC YELLOW NO. 10  FURCH YELLOW NO. 6  HYPROMELLOSES  METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)  CELLULOSE, MICRO CRYSTALLINE  MINERAL O IL  FO TASSIUM HYDRO XIDE  STARCH, CORN  PROPYLENE GLYCOL  WATER  SHELLAC	ngth			
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MINERAL OIL POTASSIUM HYDROXIDE STARCH, CORN PROPYLENE GLYCOL WATER SHELLAC				
POTASSIUM HYDRO XIDE STARCH, CORN PROPYLENE GLYCOL WATER SHELLAC				
PROPYLENE GLYCOL WATER SHELLAC				
PROPYLENE GLYCOL WATER SHELLAC				
WATER SHELLAC				
SHELLAC SHELLAC				
SILICON DIO XIDE				
SO DIUM BICARBO NATE				
STEARIC ACID				
TITANIUM DIO XIDE				
FERRIC OXIDE YELLOW				

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:59726-227-60	1 in 1 CARTON		
1	60 in 1 BOTTLE		

<b>Marketing Informat</b>	ion		
Marketing Category	Application Number or Monograph Citation	<b>Marketing Start Date</b>	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	03/01/2013	

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

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

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