

ASPIRIN LOW DOSE SAFETY COATED- aspirin tablet
P and L Development of New York Corporation (ReadyInCase)

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†**

Aspirin 81 mg

Low Dose Safety Coated

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.

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Product Label



aspirin 81 mg

Drug Facts (continued)

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Compare to the active ingredient in Bayer® Low Dose Aspirin®
NDC 59726-227-60

aspirin 81 mg low dose safety coated

pain reliever (NSAID)

*aspirin regimen

60 enteric coated tablets



Distributed by: PL Developments
200 Hicks Street
Westbury, NY 11590



PLD-D189B
FC001968

Lot No.:
Exp. Date:

Drug Facts

Active ingredient (in each tablet) Aspirin 81 mg (NSAID)* Pain reliever *nonsteroidal anti-inflammatory drug

Purpose

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

Drug Facts (continued)

■ 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

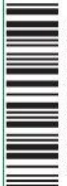
Ask a doctor or pharmacist before use if you are taking a prescription drug for ■ gout ■ diabetes ■ arthritis

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

V60X4



0 3 2 1 6 3 7 1

ReadyInCase Aspirin 81 mg Tablets

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

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80	
DIMETHICONE	
SODIUM HYDROXIDE	
SODIUM LAURYL SULFATE	
TALC	
TRIETHYL CITRATE	
ANHYDROUS LACTOSE	
FERROSFERRIC OXIDE	
BROWN IRON OXIDE	
CROSCARMELLOSE SODIUM	
D&C YELLOW NO. 10	
FD&C YELLOW NO. 6	
HYPROMELLOSES	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)	
CELLULOSE, MICROCRYSTALLINE	
MINERAL OIL	
POTASSIUM HYDROXIDE	
STARCH, CORN	
PROPYLENE GLYCOL	
WATER	
SHELLAC	
SILICON DIOXIDE	
SODIUM BICARBONATE	
STEARIC ACID	
TITANIUM DIOXIDE	
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		
2	NDC:59726-227-03	300 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	03/01/2013	

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

Revised: 7/2014

P and L Development of New York Corporation (ReadyInCase)