## SAFETY COATED ASPIRIN- as pirin tablet Valu Merchandisers Company (Best Choice)

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

- temporarily relieves minor aches and pains
- for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur

# 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:

- facial swelling
- hives
- 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

- gout
- diabetes
- arthritis

#### Stop use and ask a doctor if

• 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
- allergic reaction occurs
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- any new symptoms appear
- redness or swelling is present in the painful area

### 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 specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during the 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 unless directed by a doctor

### Other information

- store at controlled room temperature 15°-30° C (59°-86° F)
- do not use if imprinted safety seal under cap is broken or missing

### **Inactive ingredients**

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C Red # 40 Aluminum lake,FD&C Yellow # 6 Aluminum Lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, triethyl citrate

### **Questions or comments?**

# Principal Display Panel

Compare to the active ingredient in St. Joseph® Aspirin **†** 

† This product is not manufactured or distributed by McNeil Consumer & Speciality Pharmaceuticals, owner of the registered trademark ST. JOSEPH® 81 mg

See New Warnings Information

SAFETY COATED ASPIRIN

Adult Low Strength, 81 mg (NSAID)\* Aspirin Regimen\*\*

\*\*Ask your doctor before taking this product on a regular basis

- Pain reliever
- Protects against stomach upset

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

**Product Label** 



#### Enteric coated Aspirin 81 mg

SAFETY COATED ASPI aspirin tablet	RIN				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	Source)	NDC:639	941-441
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingre	dient Name		Basis of Stren	igth	Strength

		0.1
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg
Inactive Ingredients		
Ingredient Name		Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)		

CARNAUBA WAX (UNII: R12CBM0EIZ) SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)

FD&C RED NO. 40 (UNII: WZB9127XOA)

FD&C YELLOW NO.6 (UNII: H77VEI93A8)

FERRIC OXIDE RED (UNII: 1K09F3G675)

METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

**DIMETHICO NE** (UNII: 92RU3N3Y1O)

**SODIUM HYDROXIDE** (UNII: 55X04QC32I)

**SODIUM LAURYL SULFATE** (UNII: 368GB5141J)

TALC (UNII: 7SEV7J4R1U)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Color	WHITE (enteric coated peach)	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	heart;328
Contains			

Packaging				
# Item Coo	de Package Description	Marketing Start Date	Marketing End Date	
<b>1</b> NDC:63941-441-0	1 in 1 CARTON			
1	100 in 1 BOTTLE			
1	100 in I BOTTLE			

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	08/21/2010	

Labeler - Valu Merchandisers Company (Best Choice) (868703513)

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