

**ASPIRIN LOW DOSE SAFETY COATED- aspirin tablet, coated**  
**TOP CARE (Topco Associates LLC)**

*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 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 toll free **1-888-423-0139**

## **Principal Display Panel**

‡Aspirin Regimen

### **ADULT LOW DOSE**

#### **Aspirin 81 mg**

- Pain Reliever (NSAID)

Enteric Safety-Coated

ENTERIC COATED TABLETS

COMPARE TO BAYER® LOW DOSE ASPIRIN active ingredient†

†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.**

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ELK GROVE VILLAGE, IL 60007

1-888-423-0139 ©TOPCO PLV113

topcare@topcare.com

## **Product Label**

Lot No.:  
P.L.D.A.  
F0001191

Exp. Date:

0 36800 35707 5

... A portion of the proceeds from this purchase will support the Children's Miracle Network Hospitals.

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**Drug Facts (continued)**

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**Drug Facts (continued)**

**Aspirin Regimen** NDC 36800-027-12

**ADULT LOW DOSE**

# Aspirin 81mg

**• Pain Reliever (NSAID)**

**120 ENTERIC COATED TABLETS**

ASPIRIN LOW DOSE SAFETY COATED			
aspirin tablet, coated			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-027
<b>Route of Administration</b>	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
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

### 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:36800-027-12	1 in 1 BOX		
1		120 in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	03/15/2013	

**Labeler** - TOP CARE (Topco Associates LLC) (006935977)

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

Revised: 2/2013

TOP CARE (Topco Associates LLC)