

**ASPIRIN EC- aspirin tablet, coated**  
**Rebel Distributors Corp**

*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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**Aspirin EC Tablets, 81 mg**

***Drug Facts***

**Active ingredient (in each tablet)**

Aspirin 81 mg (NSAID<sup>1</sup>)

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<sup>1</sup> 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:

- 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 are taking a diuretic
- you have asthma
- you have not been drinking fluids
- you have lost a lot of fluid due to vomiting or diarrhea

**Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug
- under a doctor's care for any serious condition

**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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear
- ringing in the ears or a 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: consult a doctor

**Other information**

- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

**Inactive ingredients**

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10

aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

## Questions?

call 1-888-838-2872, weekdays, 8 AM-5 PM ET

Distributed by: **GOLDLINE LABORATORIES, INC.**, Sellersville, PA 18960

Dist. 1993 0810REV 89 387R

Repackaged by: **REBEL DISTRIBUTORS CORP**, Thousand Oaks, CA 91320

**TAMPER-EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**

\*\* This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose.

## PRINCIPAL DISPLAY PANEL - 81 mg Bottle Label



## ASPIRIN EC

aspirin tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-684(NDC:0182-1061)
Route of Administration	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
anhydrous lactose (UNII: 3S Y5LH9 PMK)	

<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>croscarmellose sodium</b> (UNII: M28OL1HH48)	
<b>D&amp;C Yellow NO. 10</b> (UNII: 35SW5USQ3G)	
<b>aluminum oxide</b> (UNII: LM26O6933)	
<b>cellulose, microcrystalline</b> (UNII: OP1R32D61U)	
<b>polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>sodium hydroxide</b> (UNII: 55X04QC32I)	
<b>sodium lauryl sulfate</b> (UNII: 368GB5141J)	
<b>talc</b> (UNII: 7SEV7J4R1U)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>triethyl citrate</b> (UNII: 8Z96QXD6UM)	

### Product Characteristics

<b>Color</b>	YELLOW	<b>Score</b>	no score
<b>Shape</b>	ROUND (Bi-convex)	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-684-30	30 in 1 BOTTLE		
2	NDC:21695-684-90	90 in 1 BOTTLE		
3	NDC:21695-684-00	100 in 1 BOTTLE		
4	NDC:21695-684-72	120 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	01/01/1993	

### Labeler - Rebel Distributors Corp (118802834)

### Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK