# BAYER GENUINE ASPIRIN- as pirin tablet R J General 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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Bayer Genuine Aspirin®

**Drug Facts** 

### Active ingredient (in each tablet)

Aspirin 325 mg  $(NSAID)^1$ 

1 nonsteroidal anti-inflammatory drug

### **Purposes**

Pain reliever/fever reducer

#### Uses

temporarily relieves

- headache
- muscle pain
- toothache
- menstrual pain
- pain and fever of colds
- minor pain of arthritis

### **Warnings**

#### Reve'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
- 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

- an allergic reaction occurs. Seek medical help right away.
- 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
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- fever lasts more than 3 days
- new symptoms occur
- 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 1 or 2 tablets every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours
- children under 12 years: consult a doctor

#### Other information

- save carton for full directions and warnings
- store at room temperature

#### **Inactive ingredients**

carnauba wax<sup>2</sup>, corn starch, hypromellose, powdered cellulose, triacetin

2 may contain this ingredient

### Questions or comments?

1-800-331-4536

(Mon – Fri 9AM – 5PM EST) or www.bayeraspirin.com

### PRINCIPAL DISPLAY PANEL - 100 Tablet Pouch Carton

GENUINE ASPIRIN BAYER®

ASPIRIN (NSAID) PAIN RELIEVER/FEVER REDUCER

THE WONDER DRUG $_{\mathbb{R}}$ 

Safe Pain Relief Plus Lifesaving Benefits

325<sup>mg</sup>

**COATED TABLETS** 



This product is repackaged by RJ General Corp, 2350 Burnet Ave., Cincinnati, Ohio 452 9 (513)621-3738 (Mon-Fri 9AM-3PM EST) from a product manufactured by Bayer. Bayer®, the Bayer Cross® and The Wonder Drug are registered trademarks of Bayer, used with permission.

#### Questions? 1-800-331-4536 or www.bayeraspirin.com

inactive ingredients: carnauba way", corn starch, hyprometose, powdered

Tamper Evident. Do not use if packet is rom, cut or opened. Store at controlled room immedity. By C. (56" to 36" F), Avoid excessive heat and hundring the presence it is "bo 0" C (56" to 86" F).

Consult a doctor	Children under 12 years
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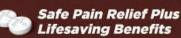
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Drug Facts

**GENUINE ASPIRIN** ASPIRIN (NSAID) PAIN RELIEVER/FEVER REDUCER

THE WONDER DRUG®













### **BAYER GENUINE ASPIRIN**

aspirin tablet

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70264-013(NDC:0280-2000)
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
STARCH, CORN (UNII: O8232NY3SJ)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)			
PO WDERED CELLULOSE (UNII: SMD1X3XO9M)			
TRIACETIN (UNII: XHX3C3X673)			

Product Characteristics				
Color	WHITE	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	BAYER	
Contains				

1	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70264-013-01	50 in 1 CARTON	07/31/2014	
1		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	07/31/2014	

## Labeler - RJ General Corporation (122542830)

Establishment				
Name	Address	ID/FEI	Business Operations	
R J General Corporation		122542830	REPACK(70264-013)	

Revised: 12/2015 R J General Corporation