

## **BAYER GENUINE ASPIRIN- aspirin tablet**

### **Select 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)<sup>1</sup>

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1 nonsteroidal anti-inflammatory drug

#### **Purposes**

Pain reliever/fever reducer

#### **Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - muscle pain
  - toothache
  - menstrual pain
  - colds
  - minor pain of arthritis
- temporarily reduces fever

#### **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
- 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
- if you have ever had an allergic reaction to this product or any of its ingredients

## **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 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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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**

corn starch, hypromellose, powdered cellulose, triacetin

**Questions?**

**1-800-331-4536** (Mon-Fri 9AM-5PM EST)

Dist. by: Bayer HealthCare LLC  
Whippany, NJ 07981

**PRINCIPAL DISPLAY PANEL - 325 mg Tablet Pouch Blister Pack**

BAYER®  
ASPIRIN (NSAID) PAIN RELIEVER/FEVER REDUCER

2  
Coated  
Tablets  
Single-Pack

GENUINE ASPIRIN  
the wonder drug®  
SAFE PAIN RELIEF + LIFESAVING BENEFITS

325  
mg

ACTUAL SIZE

Talk to your doctor or other healthcare provider  
before using this product for your heart.

Aspirin is not appropriate for everyone, so be sure to talk to your doctor before you begin an aspirin regimen.



**Bayer**  
Dist. by: Bayer HealthCare LLC  
Whippany, NJ 07981  
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**BAYER**  
ASPIRIN (NSAID) PAIN RELIEVER/FEVER REDUCER

**GENUINE ASPIRIN**  
the wonder drug™  
SAFE PAIN RELIEF + LIFESAVING BENEFITS

**325 mg**

2 Coated Tablets Single-Pack

ACTUAL SIZE

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Open Flap for **DRUG FACTS** →



Read all warnings and directions before use



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



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**Single - Pack: 2 Tablets**

This Product is repackaged by: Select Corporation  
1433 Wainwright Way, Carrollton, TX 75007  
877-244-4400 M - F 9am - 5pm, from a product manufactured by Bayer.

**Drug Facts**

**Active ingredient (in each tablet)** Aspirin 325 mg (NSAID)\* .....Pain reliever/fever reducer \*nonsteroidal anti-inflammatory drug

**Purposes**

**Uses**

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**Questions?** 1-800-331-4536 (Mon-Fri 9AM-5PM EST)

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## BAYER GENUINE ASPIRIN

aspirin tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52904-828(NDC:0280-2000)
<b>Route of Administration</b>	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
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>powdered cellulose</b> (UNII: SMD1X3XO9M)	
<b>triacetin</b> (UNII: XHX3C3X673)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	BAYER
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52904-828-04	1 in 1 BLISTER PACK	07/31/2014	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:52904-828-05	2 in 1 BLISTER PACK	07/31/2014	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:52904-828-25	25 in 1 CARTON	07/31/2014	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:52904-828-50	50 in 1 CARTON	07/31/2014	
4		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** - Select Corporation (053805599)