

**ASPIRIN- aspirin tablet**  
**Safetec of America, Inc.**

*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 325 mg (NSAID)\*

\*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**

**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

**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**

- store at room temperature 15°-30°C (59°-86°F)

**Inactive ingredients**

corn starch, povidone

**Questions or comments?**

Call toll free: **1-800-456-7077**

**Principal Display Panel - 325 mg Pouch Label**

**Safetec**  
of America, Inc.

DO NOT USE IF POUCH IS TORN OR DAMAGED

Manufactured for Safetec of America, Inc.  
Buffalo NY 14215

**Aspirin Pain Reliever/Fever Reducer**

ORIGINAL STRENGTH

2 Tablets



### Principal Display Panel – 50 Count Carton Label

Safetec®  
of America, Inc.

\*Compare to the active ingredient in  
Bayer Genuine Aspirin®

NDC 61010-4407-1

ORIGINAL STRENGTH

Aspirin

Aspirin 325 mg Pain Reliever/Fever Reducer

PUSH TO OPEN

Dispense

through opening

- Relieves minor aches and pains
- Fever reducer

TAMPER EVIDENT UNIT DOSE POUCHES

DO NOT USE IF POUCH IS TORN OR DAMAGED

50 Pouches 2 Tablets per Pouch



ORIGINAL STRENGTH

# Aspirin

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NDC 61010-4407-1

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50 Pouches 2 Tablets per Pouch

TAMPER EVIDENT UNIT DOSE POUCHES  
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- Relieves minor aches and pains
- Fever reducer

Aspirin 325 mg - Pain Reliever/Fever Reducer

# Aspirin

ORIGINAL STRENGTH



\*Compare to the active ingredient in Bayer Genuine Aspirin®

### Drug Facts (continued)

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Manufactured at an FDA registered facility by SAFETEC OF AMERICA, INC.



Buffalo NY, 14215  
www.safetec.com



ORIGINAL STRENGTH

# Aspirin

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Aspirin 325 mg - Pain Reliever/Fever Reducer

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TAMPER EVIDENT UNIT DOSE POUCHES  
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50 Pouches 2 Caplet per pouch



## Principal Display Panel – 100 Count Carton Label

Safetec®  
of America, Inc.

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Bayer Genuine Aspirin®

NDC 61010-4407-2

ORIGINAL STRENGTH

Aspirin

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- Relieves minor aches and pains
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PUSH TO OPEN

Dispense  
through opening

TAMPER EVIDENT UNIT DOSE POUCHES

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FOLD

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# ASPIRIN

aspirin tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:6 10 10-440 7
<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
starch, corn (UNII: O8232NY3SJ)	
povidone (UNII: FZ989GH94E)	

## Product Characteristics

<b>Color</b>	white (WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	ASPIRIN;1
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6 10 10-440 7-0	2 in 1 POUCH; Type 0: Not a Combination Product	12/30/20 19	
2	NDC:6 10 10-440 7-1	50 in 1 BOX	12/30/20 19	
2	NDC:6 10 10-440 7-0	2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:6 10 10-440 7-2	100 in 1 BOX	12/30/20 19	
3	NDC:6 10 10-440 7-0	2 in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part343	12/30/20 19	



