

ASPIRIN- aspirin tablet
Certified Safety Manufacturing

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.

Aspirin

Drug Facts

Active ingredient (in each tablet)

Aspirin (NSAID¹) 325 mg

¹ nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves minor aches and pains associated with

- headache
- minor arthritis pain
- common cold
- menstrual cramps
- muscular aches
- backache
- toothache

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

If an allergic reaction occurs, stop use and seek medical help right away.

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 alcohol drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you have ever had an allergic reaction to any other pain reliever/ fever reducer
- if you are taking prescription drugs for gout, diabetes or arthritis

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

- under a doctor's care for any serious condition
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- 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
- if ringing in the ears or loss of hearing occurs
- redness or swelling is present in the painful area
- any new symptoms appear

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

- **do not take more than directed**
- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- drink a full glass of water with each dose

**Adults and children:
(12 years and older)**

Take 1 or 2 tablets with water every 4 hours as needed. Do not take more than 12 tablets in 24 hours, or as directed by a doctor.

Children under 12 years:

Do not give to children under 12 years of age.

Other information

- read all product information before using
- store at room temperature 59°-86°F (15°-30°C)
- avoid excessive heat and humidity
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, mineral oil, titanium dioxide

Questions or comments?

1-800-xxx-xxxx

PRINCIPAL DISPLAY PANEL - 25 Pouch Box

Tamper evident packaging:
Do not use if open or torn.

This package for households without children

See New Warnings Information

Compare to Bayer®

CERTI-ASPIRIN™

325 mg Aspirin (NSAID)*

- Pain Reliever
- Fever Reducer



Drug Facts

Active ingredients (each tablet).....Purpose

Aspirin equal to 325 mg aspirin (NSAID*).....Pain Reliever/ Fever Reducer * nonsteroidal anti-inflammatory drug.

Uses • Temporarily relieves minor aches and pains associated with: headache • muscular aches • minor arthritis pain • toothache • backache • the common cold • menstrual cramps. • 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 • skin reddening • facial swelling • rash • asthma (wheezing) • blisters • shock. If an allergic reaction occurs, stop use and seek medical help right away.

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 (such as aspirin, ibuprofen, naproxen or others) • have 3 or more alcoholic drinks everyday while using this product • take more or for a longer time than directed.

Do not use • if you have ever had an allergic reaction to any other pain reliever/fever reducer • right before or after heart surgery • if you are taking prescription drugs for gout, diabetes or arthritis • if you are taking a steroid drug.

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: • under a doctor's care for any serious condition • taking any other drug.

Stop use and ask a doctor if • 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 for more than 10 days • fever gets worse or lasts more than 3 days • you have difficulty swallowing • ringing in the ears or loss of hearing occurs ▶

Drug Facts (continued)

• redness or swelling is present in the painful area • any new symptoms appear.

When using this product • take with food or milk if stomach upset 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 the reach of children.** In case of accidental overdose, get medical help, or contact a Poison Control Center (800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Do not exceed recommended dosage.

Directions: • use the smallest effective dose • do not take longer than 10 days, unless directed by a doctor (see warnings) • drink a full glass of water with each dose.

• Adults and Children 12 years of age and over Take 1 or 2 tablets every 4 hours as needed. Do not take more than 12 tablets in 24 hours or as directed by a doctor.

• Children under 12 years Do not give to children under 12 years of age.

Other information • read all product information before using • store at room temperature 15-30°C (59-86°F) • avoid excessive heat and humidity • use by expiration date on package.

Inactive ingredients • cellulose*, croscarmellose sodium*, hypromellose, microcrystalline cellulose*, mineral oil*, polyethylene glycol, propylene glycol*, starch, titanium dioxide*. *May contain.

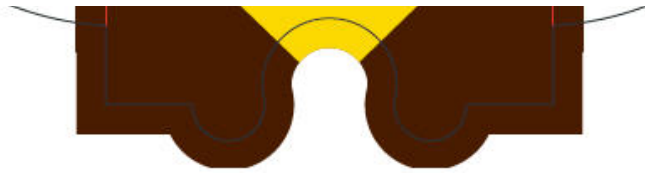
Questions? Call 1-800-854-7474

Mfg. for: Certified Safety Mfg., Inc.
Kansas City, MO 64127

Reorder # 504-041



25 TABLETS EACH
25 PACKAGES



ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48083-654
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
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Mineral Oil (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Propylene Glycol (UNII: 6DC9Q167V3)	
STARCH, CORN (UNII: O8232NY3SJ)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	TCL;011
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48083-654-66	24 in 1 BOX	12/29/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:48083-654-27	25 in 1 BOX	12/29/2017	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:48083-654-30	50 in 1 BOX	12/29/2017	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:48083-654-33	125 in 1 BOX	12/29/2017	

4		2 in 1 POUCH; Type 0: Not a Combination Product	
5	NDC:48083-654-36	250 in 1 BOX	12/29/2017
5		2 in 1 POUCH; Type 0: Not a Combination Product	
6	NDC:48083-654-39	500 in 1 BOX	12/29/2017
6		2 in 1 POUCH; Type 0: Not a Combination Product	
7	NDC:48083-654-41	1000 in 1 BOX	12/29/2017
7		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 FINAL	part343	12/29/2017	

Labeler - Certified Safety Manufacturing (788460483)

Revised: 12/2017

Certified Safety Manufacturing