

ASPIRIN- aspirin tablet
CARDINAL HEALTH

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.

Drug Facts

Active ingredient (in each tablet)

Aspirin 325mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

temporarily relieves

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

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

- facial swelling
- shock
- hives
- 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
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product

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 are taking a diuretic
- you have asthma
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease

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

- 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
- an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious illness.

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 accidental overdose, get medical help or contact a Poison Control Center (1-8000-222-1222) right away.

Directions

- drink a full glass of water with each dose

adults and children 12 years and over	take 1 to 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

Inactive ingredients

Corn starch, hypromellose, microcrystalline cellulose, stearic acid, triacetin & talc

Questions or comments?

Adverse drug event call: (866) 562-2756

†Compare to Genuine Bayer® Aspirin active ingredient

Leader Genuine Aspirin 325 mg

Pain Reliever/Fever Reducer (NSAID)

Fast, Safe Pain Relief

NDC 49781-095-51

LEADER
GENUINE
Aspirin
325 mg
Pain Reliever/Fever Reducer
(NSAID)
Fast, Safe Pain Relief

100 COATED TABLETS

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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Purpose
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Uses
temporarily relieves
 ■ minor pain of arthritis
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 ■ muscle pain
 ■ menstrual pain
 ■ toothache
 ■ pain and fever of colds

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.
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 ■ take a blood thinning (anticoagulant) or steroid drug
 ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
 ■ take more or for a longer time than directed

This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Genuine Bayer® Aspirin. ORG604/14

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund. www.myleader.com 1-800-200-6313

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PEEL HERE FOR MORE DRUG FACTS

Drug Facts (continued)

■ have had stomach ulcers or bleeding problems
 ■ have 3 or more alcoholic drinks every day while using this product

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
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 ■ you are taking a diuretic ■ you have asthma
 ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

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 ■ 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
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Directions ■ drink a full glass of water with each dose
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Other information
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Inactive ingredients corn starch, hypromellose, microcrystalline cellulose, stearic acid, triacetin & talc

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STOP PEELING

Perm Glue

ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49781-095
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
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Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIACETIN (UNII: XHX3C3X673)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	PH041
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-095-51	100 in 1 BOTTLE		
2	NDC:49781-095-58	300 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	09/20/2014	

Labeler - CARDINAL HEALTH (097537435)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Revised: 9/2014

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