

ASPIRIN- aspirin tablet, coated
Harmon Stores 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.

HAR - 1018 - 2019-1009

Drug Facts

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID) *

* nonsteroidal anti-inflammatory drug

Purpose

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:

- diabetes
- gout
- 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 for more than 10 days
- redness or swelling is present
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious condition.

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 (1-800-222-1222).

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 between 20°-25°C (68°-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

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

PRINCIPAL DISPLAY PANEL

CORE VALUES

Compare to the active ingredient in Bayer® Aspirin

Regular Strength

SAFE PAIN RELIEF

Aspirin

Consult your healthcare provider before using this product for your heart.

PAIN RELIEVER / FEVER REDUCER (NSAID)

ACTUAL SIZE

100 COATED TABLETS 325 MG EACH

INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING

F101811HAR_R3

This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer® Aspirin.

DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING



Drug Facts

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

Uses temporarily relieves:

- headache
- muscle pain
- toothache
- menstrual pain
- pain and fever of colds
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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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Ask a doctor before use if

- stomach bleeding warning applies to you

Drug Facts (continued)

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Drug Facts (continued)

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Inactive ingredients

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

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CORE VALUES™

Compare to the active ingredient in Bayer® Aspirin†

Regular Strength

Aspirin

SAFE PAIN RELIEF

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PAIN RELIEVER / FEVER REDUCER (NSAID)

ACTUAL SIZE

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COATING FREE AREA

ASPIRIN

aspirin tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63940-320

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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL;011
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-320-11	1 in 1 CARTON	11/09/2009	05/31/2025
1		100 in 1 BOTTLE, PLASTIC; 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	11/09/2009	05/31/2025

Labeler - Harmon Stores Inc. (804085293)