

ASPIRIN REGULAR STRENGTH- aspirin tablet, coated

Major Pharmaceuticals

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 325 mg (NSAID)*

***nonsteroidal anti-inflammatory drug**

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscle pain
 - toothache
 - menstrual pain
 - colds
 - minor arthritis pain
- or as recommended by a doctor

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
- shock
- 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
- 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
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

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

- adults and children 12 years of age and over: take 1 to 2 tablets every 4 hours, while symptoms persist.
- drink a full glass of water with each dose.
- do not take more than 12 tablets in 24 hours unless directed by a doctor
- children under 12 years of age: do not use

Other information

- store between 20-25°C (68-77°F)

Inactive ingredients

corn starch, croscarmellose sodium, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Questions or comments?

Call **1-877-753-3935 Monday-friday 9AM-5PM EST**

Principal Display Panel

Compare to the active ingredient in Ecotrin®[†]

Aspirin 325 mg

Regular Strength

pain reliever (NSAID)

Aspirin Regimen[≠]

Safety coated^{**}

Tablets

[†]This product is not manufactured or distributed by Prestige Brands, Inc., distributor of Ecotrin®.

^{**}Coating helps protect against stomach upset

[≠]Talk to your doctor or other healthcare provider before using this product for your heart. Aspirin is not right for everyone. .

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BORKEN OR MISSING.

Distributed by: Major® Pharmaceuticals

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

Package label

MAJOR
 NDC 0904-6712-60
 Compare to the active ingredient in Ecotrin®*

Aspirin 325 mg
Regular Strength
 Pain reliever (NSAID)
 Aspirin regiment
 Safety coated**

100 Tablets

Distributed by Major Pharmaceuticals
 17177 N Laurel Park Drive Suite 233
 Livonia, MI 48152
 Rev. 02/18 M-58
 Re-order No. 700877

PDU-A1350
 LB005725 3
 0604671260
 2

Lot No.:
 Exp. Date:

OPEN HERE TO VIEW COMPLETE PRODUCT INFORMATION

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 *nonsteroidal anti-inflammatory drug

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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

Drug Facts (continued)
 ■ 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
 ■ you are pregnant or breastfeeding ■ symptoms occur ■ you are taking aspirin ■ you are taking aspirin ■ you are taking aspirin ■ you are taking aspirin
 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.
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MAJOR Aspirin 325 mg Regular Strength

ASPIRIN REGULAR STRENGTH			
aspirin tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6712
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		
STARCH, CORN (UNII: O8232NY3SJ)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			

METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6712-60	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2018	12/27/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/31/2018	12/27/2024

Labeler - Major Pharmaceuticals (191427277)

Revised: 10/2021

Major Pharmaceuticals