

**ASPIRIN- aspirin tablet, film 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.*

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**Major Pharmaceuticals Aspirin 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 have ever had an allergic reaction to any other pain reliever/fever reducer

**Ask a doctor before use if**

- you have asthma
- you are taking a diuretic
- 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

**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 gets worse or lasts more than 3 days
  - new symptoms occur
  - ringing in the ears or a 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 at 20°-25°C (68°-77°F)

**Inactive ingredients**

corn starch, dibasic calcium phosphate dihydrate, hypromellose, talc, triacetin

**Questions or comments?**

**1-800-616-2471**

**Principal Display Panel**

Compare to Bayer® Aspirin active ingredient

ADULT

ASPIRIN

Pain Reliever/Fever Reducer (NSAID)

Safe Pain Relief Plus Lifesaving Benefits

Talk to your doctor or other healthcare provider before using this product for your heart.

325 mg each

500 Tablets

TEMPORARILY RELIEVES HEADACHES AND EVERYDAY ACHES & PAINS

**MAJOR**<sup>®</sup> NDC 0904-6809-40  
Compare to Bayer<sup>®</sup> Aspirin active ingredient\*\*

**ADULT**  
**ASPIRIN**  
Pain Reliever/  
Fever Reducer  
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TEMPORARILY RELIEVES  
HEADACHES AND  
EVERYDAY ACHES & PAINS

41690 5C F1

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

**Drug Facts**

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

**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)  take more or for a longer time than directed  
 have 3 or more alcoholic drinks every day while using this product

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer  
**Ask a doctor before use if**  
 you have asthma  
 you are taking a diuretic



PEEL BACK HERE

GLUE AREA

**Drug Facts (continued)**

- 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

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
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  - fever gets worse or lasts more than 3 days
  - new symptoms occur
  - ringing in the ears or a 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.  
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**Drug Facts (continued)**

**Directions**

- drink a full glass of water with each dose
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- children under 12 years: consult a doctor

**Other information**  store at 20°-25°C (68°-77°F)

**Inactive ingredients** corn starch, dibasic calcium phosphate dihydrate, hypromellose, talc, triacetin

**Questions or comments?** 1-800-616-2471

\*\*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Bayer<sup>®</sup> Aspirin.

Distributed by  
**MAJOR<sup>®</sup> PHARMACEUTICALS**  
 17177 N Laurel Park Drive, Suite 233  
 Livonia, MI 48152  
 M-05 REV. 09/18  
 Re-Order No. 701010

GLUE AREA

GLUE AREA

GLUE AREA

**ASPIRIN**

aspirin tablet, film coated

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6809
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)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TALC (UNII: 7SEV7J4R1U)	
TRIACETIN (UNII: XHX3C3X673)	

### Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	14mm
Flavor		Imprint Code	Aspirin;L
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6809-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2018	

### Marketing Information

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

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 3/2019

Major Pharmaceuticals