

LOW DOSE ASPIRIN- 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 81 mg (NSAID)*

***nonsteroidal anti-inflammatory drug**

Purpose

Pain reliever

Uses

- for the temporary relief of minor aches and pains or as recommended by your doctor. **Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.**
- ask your doctor about other uses for safety coated 81 mg aspirin

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 have asthma
- you are taking a diuretic

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 stool
 - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- ringing in the ears or loss of hearing occurs
- new symptoms occur

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 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: do not use

Other information

- store between 15-30°C (59-86°F)

Inactive ingredients

anhydrous lactose**, black iron oxide**, brown iron oxide**, corn starch**, croscarmellose sodium**, D&C yellow #10, FD&C yellow #6**, hypromellose**, methacrylic acid copolymer, microcrystalline cellulose, mineral oil**, pharmaceutical ink**, polysorbate 80**, potassium hydroxide**, propylene glycol**, purified water**, shellac**, silicon dioxide, simethicone**, sodium bicarbonate**, sodium hydroxide**, sodium lauryl sulfate**, stearic acid**, talc, titanium dioxide, triethyl citrate, yellow iron oxide**

**contains one or more of these ingredients

Questions or comments?

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

Principal Display Panel

Compare to the active ingredient in Bayer® Low Dose Aspirin†

Aspirin 81 mg

Low Dose

Pain reliever **(NSAID)**

Aspirin regimen[±]

Enteric Coated^{±±}

Safety coated

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

≠≠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 BROKEN OR MISSING

Distributed by:

Major® Pharmaceuticals

17177 N Laurel Park Drive,

Suite, Livonia MI 48152

Product Label

OPEN HERE TO VIEW COMPLETE PRODUCT INFORMATION

Exp. Date: _____

Lot No.: _____

P.D.-A1880
L8005722 3 09046713180

MAJOR® NDC 0904-6713-18
Compare to the active ingredient
in Bayer® Low Dose Aspirin®



Aspirin 81 mg
Low Dose
Pain reliever (NSAID)
Aspirin regimen†
Enteric coated‡
Safety coated

120 Tablets

Rev. 02/18 R-58
Re-order No. 700878

Distributed by:
Major Pharmaceuticals
17177 N Laurel Park Drive,
Suite 233
Livonia, MI 48152

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nonsteroidal anti-inflammatory drug

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‡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.

Drug Facts (continued)

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 had high blood pressure, heart disease, liver, kidney disease ■ you are taking a diuretic ■ you are taking a prescription drug for diabetes ■ arthritis ■ joint pain ■ diabetes ■ you are pregnant or breastfeeding, 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).

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MAJOR Aspirin 81 mg Low Dose

LOW DOSE ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6713
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	
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)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	E;T81;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6713-18	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2018	02/28/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	02/28/2018	02/28/2025

Labeler - Major Pharmaceuticals (191427277)