

ASPIRIN LOW DOSE- aspirin tablet, delayed release

Major Pharmaceuticals

Major 44-600A

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.**

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

- take more or for a longer time than directed
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have asthma
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- 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:
 - vomit blood
 - have bloody or black stools
 - feel faint
 - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- new symptoms occur
- 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 at 20 weeks or later in 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.

Directions

- **do not take more than directed**
- 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 unless directed by a doctor

Other information

- use by expiration date on package

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

corn starch, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, silica, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

(800) 616-2471

Principal Display Panel

Major®

NDC 0904-6751-80

ASPIRIN

Low Dose

PAIN RELIEVER (NSAID)

81 mg

Enteric Coated

Safety Coated

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

Actual Size

1000 Tablets

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

†This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer® Low Dose Aspirin. 50844 REV0122A60016

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152 USA M-17

Rev. 05/18 Re-order No. 700939

MAJOR®

NDC 0904-6751-80

ASPIRIN

Low Dose

PAIN RELIEVER (NSAID)
81 mg

Enteric Coated
Safety Coated

Actual Size



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■ hives ■ facial swelling ■ shock ■ asthma (wheezing)
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Do not use ■ if you are allergic to aspirin or any other pain reliever/fever reducer ■ if you have ever had an allergic reaction to this product or any of its ingredients
Ask a doctor before use if ■ stomach bleeding warning applies to you ■ you have asthma ■ you have a history of stomach problems, such as heartburn ■ you are taking a diuretic ■ 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

Sign 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: ■ vomit blood ■ have bloody or black stools ■ feel faint ■ have stomach pain that does not get better ■ ringing in the ears or a loss of hearing occurs ■ new symptoms occur ■ 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 at 20 weeks or later in 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.

Directions ■ do not take more than directed ■ 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 unless directed by a doctor
Other information ■ use by expiration date on package ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients corn starch, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, silica, smectone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments? (800) 616-2471

MAJOR PHARM, INC. 1777 N. Central Expressway, Suite 203, Irving, TX 75038
Aspirin 81 mg (NSAID) 1000 Tablets (NDC 0904-6751-80)
The product is not manufactured or distributed by Bayer AG, owner of the Bayer logo.
Phar. 05/18 Rev. 01/18
MAJOR PHARM, INC. 1777 N. Central Expressway, Suite 203, Irving, TX 75038



major 44-600A

ASPIRIN LOW DOSE

aspirin tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6751
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
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SHELLAC (UNII: 46N107B710)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	yellow	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	L
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6751-80	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2011	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/01/2011	

Labeler - Major Pharmaceuticals (191427277)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0904-6751)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0904-6751)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(0904-6751) , pack(0904-6751)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0904-6751)