

ASPIRIN LOW DOSE- aspirin tablet, coated

MAJOR PHARMACEUTICALS

maj 981

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
- ask your doctor about other uses for 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
- 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 your are allergic to aspirin or any other pain reliever/fever reducer.

Ask a doctor before use if

- the stomach bleeding warning applies to you

- you are taking a diuretic
- you have a history of stomach problems, such as heartburn
- you have: -high blood pressure -heart disease -liver cirrhosis -kidney disease -asthma

Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- taking a prescription drug for diabetes, gout or arthritis

Stop use and ask a doctor if

- 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
- an allergic reaction occurs. Seek medical help right away
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

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.

Directions

- drink a full glass of water with each dose
- swallow whole, do not chew or crush
- do not exceed recommended dose
- adults and children 12 years and older: take 4-8 tablets every 4 hours, as needed, not more than 48 tablets in 24 hours, or as directed by a doctor
- children under 12 years: ask a doctor

Other information

- store at controlled room temperature

Inactive ingredients

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

package label

NDC 0904-6783-70

MAJOR

ASPIRIN
Low Dose

PAIN RELIEVER (NSAID)
81 mg

Enteric Coated
Safety Coated

Compare to the active ingredient in
BAYER® Low Dose Aspirin**
250 Tablets

Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

Drug Facts

Active ingredient (in each tablet) Aspirin 81 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

Uses ■ for the temporary relief of minor aches and pains ■ ask your doctor about other uses for 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 ■ 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 ■ the stomach bleeding warning applies to you ■ you are taking a diuretic ■ you have a history of stomach problems, such as heartburn ■ you have: ■ high blood pressure ■ heart disease ■ liver cirrhosis ■ kidney disease ■ asthma

** This product is not manufactured or distributed by the owner of the registered trademark Bayer® Low Dose.

Distributed by **MAJOR**® PHARMACEUTICALS

17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152

Re-Order No. 700996

Rev. 09/18

M-99



PEEL HERE FOR MORE DRUG FACTS

STOP PEEING

Questions or comments? 1-800-616-2471

Other information ■ store at controlled room temperature

Inactive ingredients: cellulose, D&C yellow #10, FD&C yellow #6, hypromellose, methacrylic acid, PEG, polyvinylpyrrolidone, silica, simethicone, sodium bicarbonate, sodium lauryl sulfate, starch, talc, titanium dioxide, triacetin, triethyl citrate, wax.

children under 12 ask a doctor

adults and children 12 years and older take 4-8 tablets every 4 hours, as needed, not more than 48 tablets in 24 hours, or as directed by a doctor

Directions
■ drink a full glass of water with each dose
■ swallow whole, do not chew or crush
■ do not exceed recommended dose

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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.

Stop use and ask a doctor if ■ 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 ■ an allergic reaction occurs. Seek medical help right away; ■ pain gets worse or lasts more than 10 days ■ redness or swelling is present ■ fever gets worse or lasts more than 3 days ■ any new symptoms occur ■ ringing in the ears or loss of hearing occurs

Ask a doctor or pharmacist before use if you are ■ taking any other drug containing an NSAID (prescription or nonprescription) ■ taking a blood thinning (anticoagulant) or steroid drug ■ taking a prescription drug for diabetes, gout or arthritis

Drug Facts (continued)

Stop use and ask a doctor if ■ 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 ■ an allergic reaction occurs. Seek medical help right away; ■ pain gets worse or lasts more than 10 days ■ redness or swelling is present ■ fever gets worse or lasts more than 3 days ■ any new symptoms occur ■ ringing in the ears or loss of hearing occurs

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ASPIRIN LOW DOSE

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6783
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
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:0904-6783-70	250 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/01/2018	

Labeler - MAJOR PHARMACEUTICALS (191427277)

Registrant - Geri-Care Pharmaceutical Corp (611196254)