

LOW DOSE ASPIRIN- aspirin tablet, coated
Akron Phama

Low Dose Aspirin
81 mg
Pain Reliever (NSAID)
Safety Coated Aspirin Regimen

Drug Facts

Active Ingredient (in each tablet)

Aspirin 81 mg (NSAID)*

*** nonsteroidal anti-inflammatory drug**

***Purpose* Pain reliever**

Uses

- temporarily relief of minor aches and pains or as recommended by your doctor.
Because of its delayed release action, this product will not provide fast relieve of headache or 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 the 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
- shock
- facial swelling
- asthma (wheezing)

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. This 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 of 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

- you have asthma
- 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

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, or arthritis
- under a doctor's care for any serious condition
- taking any other drug

Stop use and ask a doctor if

- 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
- an allergic reaction occurs. Seek medical help right away.
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- redness or swelling present in the painful area
- 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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 while symptoms last
- do not take more than 48 tablets in 24 hours unless directed by a doctor
- **children under 12 years:** ask a doctor

Other information

- store at room temperature 15 °-30 °C(59 °-86 °F)
- read all product information before using
- **TAMPER EVIDENT:** Do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

Croscarmellose Sodium, Colloidal Silicon Oxide, Castor oil, Diethyl Phthalate, Dichloromethane, FD&C yellow 6 lake, Hydroxypropyl Methylcellulose Phthalate,

Isopropyl Alcohol, Lactose Monohydrate, Propylene glycol, Sodium Starch Glycolate, Starch, Titanium Dioxide, Talc

Questions or comments? Call toll-free 1-877-225-6999, Monday to Friday 9AM to 5PM

• This product is not manufactured or distributed by Bayer HealthCare LLC., owner of the registered trademark Bayer® Low Dose Aspirin.

<p>Drug Facts (Continued)</p> <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> you have asthma 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 <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> taking a prescription drug for diabetes, gout, or arthritis under a doctor's care for any serious condition taking any other drug <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> feel faint have bloody or black stools vomit blood have stomach pain that does not get better an allergic reaction occurs. Seek medical help right away. ringing in the ears or loss of hearing occurs pain gets worse or lasts for more than 10 days fever gets worse or lasts for more than 3 days redness or swelling present in the painful area new symptoms occur <p>These could be signs of a serious condition.</p> <p>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.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222)</p> <p>Directions</p> <ul style="list-style-type: none"> drink a full glass of water with each dose adults and children 12 years and over: <ul style="list-style-type: none"> take 4 to 8 tablets every 4 hours while symptoms last do not take more than 48 tablets in 24 hours unless directed by a doctor children under 12 years: ask a doctor. <p>Other information</p> <ul style="list-style-type: none"> store at room temperature 15°-30°C (59°-86°F) read all product information before using <p>Inactive ingredients: Croscarmellose Sodium, Colloidal Silicon Dioxide, Castor oil, Dihydrate, Dichloromethane, FD&C yellow 6 dye, Hydroxypropyl Methylcellulose Phthalate, Isopropyl Alcohol, Lactose Monohydrate, Propylene glycol, Sodium Starch Glycolate, Starch, Titanium Dioxide, Talc</p> <p>Questions or comments? Call toll-free 1-877-225-6999 Monday to Friday 9AM to 5PM</p>
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<p>Akron Pharma NDC 71399-1003-2</p> <p>Compare to Bayer® Low Dose Aspirin active ingredient*</p> <p>Low Dose Aspirin 81 mg</p> <p>Pain Reliever (NSAID)</p> <p>Safety Coated Aspirin Regimen</p> <p>120 Tablets</p>	<p>Drug Facts</p> <p>Active ingredient (in each tablet) Aspirin 81 mg (NSAID)* Pain reliever * nonsteroidal anti-inflammatory drug</p> <p>Uses</p> <ul style="list-style-type: none"> temporarily relief of minor aches and pains or as recommended by your doctor. Because of its delayed release action, this product will not provide fast relief of headache or symptoms needing immediate relief. <p>Warnings</p> <p>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.</p> <p>Allergy alert: Aspirin may cause a severe allergic reaction, which may include: <ul style="list-style-type: none"> hives shock facial swelling asthma (wheezing). Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> if you are allergic to aspirin, or any other pain reliever/fever reducer <p>DRUG FACTS CONTINUED on back of the label</p> <p>TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING</p> <p>*This product is not manufactured or distributed by Bayer HealthCare LLC., owner of the registered trademark Bayer® Low Dose Aspirin.</p> <p>Akron Pharma Manufactured for: Akron Pharma, Inc. Fairfield, NJ 07004 www.akronpharma.com Rev: 3/24</p> <p>PEEL HERE</p> <p>71399-1003-2</p> </p>
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Akron Pharma NDC 71399-1003-1

Compare to Bayer® Low Dose Aspirin active ingredient*

Low Dose Aspirin 81 mg

Pain Reliever (NSAID)

Safety Coated Aspirin Regimen

SEE NEW WARNINGS INFORMATION

1000 Tablets

Drug Facts
Purpose Pain reliever
Active ingredient (in each tablet) Aspirin 81 mg (NSAID)* *nonsteroidal anti-inflammatory drug
Uses ■ temporarily relief of minor aches and pains or as recommended by your doctor. Because of its delayed release action, this product will not provide fast relief of headache or 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 ■ shock ■ facial swelling ■ 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 ■ you have asthma ■ 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 Ask a doctor or pharmacist before use if you are ■ taking a prescription drug for diabetes, gout, or arthritis ■ under a doctor's care for any serious condition ■ taking any other drug Stop use and ask a doctor if ■ 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 ■ an allergic reaction occurs. Seek medical help right away. ■ ringing in the ears or loss of hearing occurs ■ pain gets worse or lasts for more than 10 days ■ fever gets worse or lasts for more than 3 days ■ redness or swelling present in the painful area ■ new symptoms occur... These could be sign 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. 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 while symptoms last ■ do not take more than 48 tablets in 24 hours unless directed by a doctor ■ children under 12 years: ask a doctor. Other information ■ store at room temperature 15°-30°C (59°-86°F) ■ read all product information before using ■ TAMPER EVIDENT: Do not use if imprinted safety seal under cap is broken or missing Inactive ingredients Croscarmellose Sodium, Colloidal Silicon Dioxide, Castor Oil, Diethyl Phthalate, Dichloromethane, FD&C yellow 6 al lake, Hydroxypropyl Methylcellulose Phthalate, Isopropyl Alcohol, Lactose Monohydrate, Propylene glycol, Sodium Starch Glycolate, Starch, Titanium Dioxide, Talc
Questions or comments? Call toll-free 1-877-225-6999, Monday to Friday 9AM to 5PM

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Akron Pharma
Manufactured for:
Akron Pharma
Fairfield, NJ 07004
www.akronpharma.com
Rev. 04/24

LOW DOSE ASPIRIN			
aspirin tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-1003
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
	CROSCARMELOSE SODIUM (UNII: M28OL1HH48)		
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
	CASTOR OIL (UNII: D5340Y2I9G)		
	DIETHYL PHTHALATE (UNII: UF064M00AF)		
	METHYLENE CHLORIDE (UNII: 588X2YUY0A)		
	FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)		
	HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST) (UNII: 87Y6436BKR)		
	ISOPROPYL ALCOHOL (UNII: ND2M416302)		
	LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
	SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)		
	STARCH, CORN (UNII: O8232NY3SJ)		
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
	TALC (UNII: 7SEV7J4R1U)		
Product Characteristics			

Color	yellow	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	A1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-1003-1	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2024	
2	NDC:71399-1003-2	120 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/01/2024	

Labeler - Akron Phama (067878881)

Revised: 7/2024

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