# LOW DOSE ASPIRIN- aspirin tablet, coated Akron Phama

-----

**Aspirin** 

Low Dose

#### **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: Asiprin 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, ibuprofin, 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 that 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 20 °-25 °C(68 °-77 °F)
- read all product information before using

### Inactive ingredients

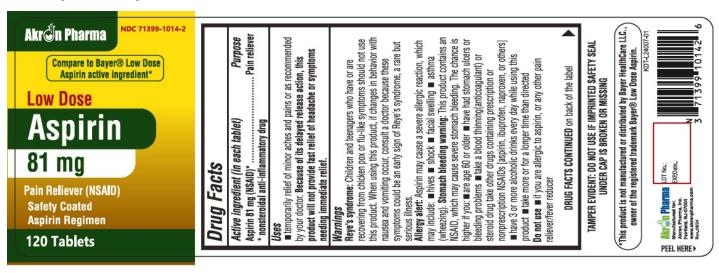
Anhydrous Lactose, Castor oil, Colloidal Silicon Dioxde, Croscarmellose Sodium, Diethyl phthalate, FD&C yellow 10 aluminium lake, Hydroxy propyl methyl cellulose, Methacrylic acid copolymer, Microcrystalline cellulose, Po~ethylene glycol, Polysorbate 80, Talc, Titanium dioxide.

#### Questions or comments? Call toll-free 1-877-225-6999

Monday to Friday 9AM to 5PM

Questions or comments? Call toll-free 1-877-225-6999

Monday to Friday 9AM to 5PM





inactive ingredients

Purpose

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID) \*nonsteroidal anti-infla

Pain reliever

■ Store at 20°-25°C (68°-77°F)
■ read all product information before using

Other information children under 12 years: ask a doctor.

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

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

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

inging 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

Seek medical help right away an allergic reaction occurs

new symptoms occu

hese could be signs of a serious condition

■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ have bloody or black stools ■ vomit

Stop use and ask a doctor i

taking any other drug

blood ■ have stomach pain that does not get better

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

Ask a doctor or pharmacist before use if you are

complications during delivery

Rege's syndrome: Children and benagers who have or are recovering from chicken pox or flu-like symptoms should not use fils pould. When may fill significant children is the plantage of the state of th

USES ■ temporarily relief of minor acties 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

Do not use mit you are allergic to aspuint, or any other pain relevent ever 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 hearthurn ■ you have high blood pressure, heart
disease, liver cirrhosis or kidney disease ■ you are taking a diuretic

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:

■ teel faint ≡ have bloody or black stools ≡ vomit blood ≡ have stomach pain that does not get better Ask a doctor or pharmacist before use if you are Itaking a prescription drug for diabetes, gout, or

■an allergic reaction occurs. Seek medical help right away. ■ eninging in the easor forsol hearing occurs a papin gets worse or lasts for more than 10 days ■eninging the easor forsol hearing occurs a papin gets worse or swelling present in the painful area

If pregnant or breast-leeding, 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. occur. These could be sign of a serious condition.

**s out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center 00-222-1222) right away, Quick medical attention is critical for adults as well as for children even if

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. ou do not notice any signs or symptoms

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

cap is broken

inted safety seal under

Inactive ingredients Amydrous Lactose, Castor Oll, Colloidal Silicon Dioxide, Crossammellose Sodium, Debthy Indakate, RDS (1994) of alaminima like, Ingroup propy methy cellulose, Menfanzynic and cooloney, Microrystalline cellulose, Polyethylene glycol, Polyeotrate 03, Talc, Trainim dioxide, Questions or comments? Call toll-free 1-877-225-6999, Monday to Friday 9AM to 5PM

manufactured or distributed by Bayer HealthCare

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

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

Ask a doctor before use if Drug Facts (Continued)

you have asthma

or kidney disease

:XPDate : LOT No.:

ZM

AKroin Pharma
Manufactured for:
Akron Pharma, Inc.
Fairfield, N-07004

## LOW DOSE ASPIRIN

aspirin tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-1014
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)			
CASTOR OIL (UNII: D5340Y2I9G)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
DIETHYL PHTHALATE (UNII: UF064M00AF)			
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)			
HYDROXYPROPYL METHYLCELLULOSE (UNII: 3NXW29V3WO)			
METHACRYLIC ACID (UNII: 1CS02G8656)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics				
Color	yellow	Score	no score	
Shape	ROUND	Size	4mm	
Flavor		Imprint Code	81	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399- 1014-2	120 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2024	
2	NDC:71399- 1014-1	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/06/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/06/2024	

# Labeler - Akron Phama (067878881)

Revised: 12/2024 Akron Phama