# LOW DOSE ASPIRIN- aspirin tablet, coated Strategic Sourcing Services LLC

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.

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# **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.
- if you have ever had an allergic reaction to his product or any of its ingredients

# 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 are taking a diuretic
- you have asthma

# 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
- fever get worse or lasts more than 3 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 at during the last 3 month 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.

## **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: consult a doctor

### Other information

• store between 15-30°C (59-86°F)

# **Inactive ingredients**

croscarmellose sodium, D&C yellow #10, lactose monohydrate, methacrylic acid, microcrystalline cellulose 102, polacrilin potassium, polyethylene glycol 6000, polyvinyl alcohol, purified talc, silicon dioxide, sodium lauryl sulfate, soybean, titanium dioxide, triethyl citrate

# Questions or comments?

Call **1-833-358-6431** Monday to Friday 9:00am to 7:00pm EST

# **Principal Display Panel**

# COMPARE TO BAYER® LOW DOSE ASPIRIN ACTIVE INGREDIENT

## **LOW DOSE**

Aspirin 81 mg

PAIN RELIEVER (NSAID)

Aspirin regimen±

**Enteric coated±±** 

Safety coated±±

### **TABLETS**

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

≠Talk to your doctor or other healthcare provider before using this product for your heart. Aspirin is not right for everyone.

≠≠Coating helps protect against stomach upset

# TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: McKesson Corp.,

via Strategic Sourcing Services LLC. Memphis, TN 38141

www.fosterand thrive.com

# **Product Label**

Exp. Date Lot No.:

Rev 03/23 PLD-A730A FC008594



Sourcing Services LLC. Memphis, TN 38141 Money Back Guarantee Distributed by: McKesson Corp., via Strategic ©2023 McKesson Corporation www.fosterandthrive.com

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 high blood pressure, heart disease, liver cirrhosis

Ask a doctor or pharmacist before use if you are taking prescription drug for gout diabetes arthritis

# Stop use and ask a doctor if

- have bloody or black stools
- pain gets worse or lasts more than 10 days
- ringing in the ears or loss of hearing occurs
- These could be signs of a serious condition.

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ACTUAL SIZE

120 TABLETS

NSAIDs (aspirin, ibuprofen, naproxen, or others)

Orug Facts (continued)

Purpose

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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

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81 mg aspirir Varnings

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syndrome, a rare but serious illness.

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# Drug Facts (continued)

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# Questions or comments?

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#Coating helps protect against stomach upset

AMPER EVIDENT: DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSI

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

NDC 70677-1150-1

Active ingredien

Orua Facts

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Foster & Thrive

**LOW DOSE** 

Aspirin regiment Enteric coated# Safety coated#

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chance is higher if you:

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have had stomach ulcers or bleeding problems

Aspirin 81 mg PAIN RELIEVER (NSAID)

### **FOSTER & THRIVE Low Dose Aspirin**

# **LOW DOSE ASPIRIN**

aspirin tablet, coated

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Prod	ILICT	Inform	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70677-1150

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
OW NO. 10 (HNII) 255 (MEHSO 2C)	

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)

CROSCARMELLOSE SODIUM (UNII: M280L1HH48)
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

METHACRYLIC ACID (UNII: 1CS02G8656)

**SILICON DIOXIDE** (UNII: ETJ7Z6XBU4)

POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)

SOYBEAN (UNII: L7HT8F1ZOD)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

## **Product Characteristics**

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

**Contains** 

# **Packaging**

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:70677- 1150-2	1 in 1 BOX	04/01/2023		
	1		180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
ı		NDC.70677				

2	NDC:/00//- 1150-3	1 in 1 BOX	04/01/2023	
2		300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:70677- 1150-1	1 in 1 BOX	04/01/2023	
3		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	04/01/2023	

# **Labeler -** Strategic Sourcing Services LLC (116956644)

Revised: 5/2023 Strategic Sourcing Services LLC