

## **ASPIRIN LOW STRENGTH ADULT- aspirin tablet, coated**

**Sam's West Inc**

*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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### **Members Mark 44-600A-Delisted**

#### ***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

#### ***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:

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

#### **Do not use**

if you are allergic to aspirin or any other pain reliever/fever reducer.

#### **Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have asthma
- 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

- gout
- diabetes
- 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.
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present

The 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.

***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: do not use unless directed by a doctor

***Other information***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

***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?***

**1-800-426-9391**

***Principal Display Panel***

**Compare to BAYER® Low Dose  
Aspirin 81 mg active ingredient†**

**M®**

NDC 68196-900-51

**low strength adult  
aspirin**

tablets, 81 mg

pain reliever

**(NSAID)**

- Enteric safety coated
- Aspirin regimen

actual  
size

**365**

**Tablets**

**NOT FOR INDIVIDUAL SALE**

**Comments or Questions? Call 1-800-426-9391  
from 8:30 a.m. to 4:00 p.m. ET Monday-Friday**

**DISTRIBUTED BY:**

**SAM'S WEST, INC.,**



**BENTONVILLE, AR 72716**

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

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

50844    ORG061360051

**Compare to BAYER® Low Dose Aspirin 81 mg active ingredient†**

actual size

**365 Tablets**

NDC 68196-900-51

**low strength adult aspirin**

tablets, 81 mg pain reliever (NSAID)

- Enteric safety coated
- Aspirin regimen

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**Drug Facts**

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\* nonsteroidal anti-inflammatory drug

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†This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose Aspirin.  
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**PEEL HERE FOR MORE DRUG FACTS**

**Drug Facts (continued)**

- take a blood thinning (anticoagulant) or steroid drug
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

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**Ask a doctor or pharmacist before use if you are taking a prescription drug for**

- gout ■ diabetes ■ arthritis

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 ■ have stomach pain that does not get better
- an allergic reaction occurs. Seek medical help right away.
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days

**STOP PEELING**

**Drug Facts (continued)**

- redness or swelling is present

These could be signs of a serious condition.

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**Questions or comments?**  
1-800-426-9391

Members Mark 44-600

## ASPIRIN LOW STRENGTH ADULT

aspirin tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-900
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: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	ROUND	Size	6 mm
Flavor		Imprint Code	L
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-900-51	2 in 1 PACKAGE	05/01/2011	01/14/2022
1		365 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/01/2011	01/14/2022

Labeler - Sam's West Inc (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(68196-900)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(68196-900) , PACK(68196-900)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(68196-900)

Revised: 1/2020

Sam's West Inc