ASPIRIN LOW DOSE- aspirin tablet, coated Chain Drug Consortium

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.

Premier Value 44-600A

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.**

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

- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product

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 this 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 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

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
 - feel faint
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- 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.

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

Premier Value®

[†]COMPARE TO THE ACTIVE INGREDIENT IN BAYER® LOW DOSE ASPIRIN

Low Dose Aspirin 81 mg PAIN RELIEVER **(NSAID)** Enteric coated

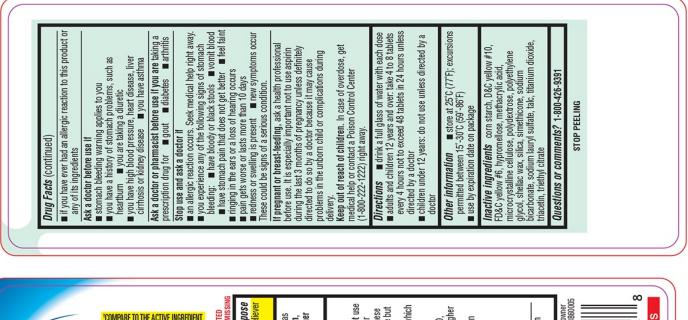
400 Tablets

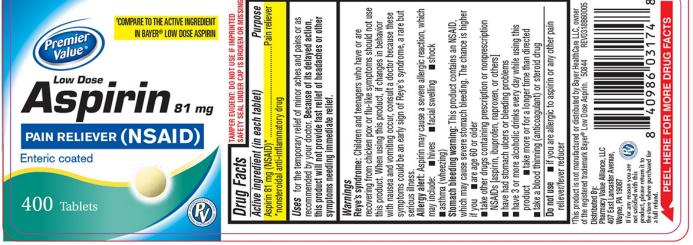
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

[†]This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Low Dose Aspirin. 50844 REV0318B60005

Distributed By: Pharmacy Value Alliance, LLC 407 East Lancaster Avenue, Wayne, PA 19087

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.





Premier Value 44-600

aspirin tablet, coated					
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:68	016-642
Route of Administration	ORAL				
Active Ingredient/Active					
I	Ingredient Name		Basis of Stre	ngth	Strengtl
			ASPIRIN		81 mg
	SPIRIN - UNII:R16CO5Y76E)				011115
ASPIRIN (UNII: R16CO5Y76E) (A	.SPIRIN - UNII:R16CO5Y76E)				ormg
ASPIRIN (UNII: R16CO5Y76E) (A	SPIRIN - UNII:R16CO5Y76E)				01 mg
ASPIRIN (UNII: R16CO5Y76E) (A	SPIRIN - UNII:R16CO5Y76E) Ingredient Name				Strength
ASPIRIN (UNII: R16CO5Y76E) (A Inactive Ingredients STARCH, CORN (UNII: 08232NY	Ingredient Name				

METHACRYLIC ACID	(UNII: 10	CS02G8656)					
MICROCRYSTALLINI	E CELLU	J LOSE (UNII: OP1	R32D61U)				
POLYDEXTROSE (UN	III: VH2X	OU12E)					
POLYETHYLENE GLY	YCOL, U	NSPECIFIED (UN	II: 3WJQ0SDW1A)				
TALC (UNII: 7SEV7J4R	R1U)						
FITANIUM DIO XIDE (UNII: 15F	FIX9 V2JP)					
TRIACET IN (UNII: XH)	X3C3X67	73)					
FRIETHYL CITRATE	(UNII: 8Z	296QXD6UM)					
SO DIUM BICARBO NA	TE (UNI	II: 8MDF5V39QO)					
SODIUM LAURYL SU	LFATE (UNII: 368GB5141J)				
FD&C YELLOW NO.	6 (UNII: I	H77VEI93A8)					
SHELLAC (UNII: 46 N10	07B71O)						
SILICON DIO XIDE (U	NII: ETJ7	SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)					
DIMETHICONE (UNII: 92RU3N3Y1O)							
DIMETHICO NE (UNII:	92RU3N	3Y1O)					
		3Y1O)					
DIMETHICONE (UNII: WATER (UNII: 059QF0		3Y1O)					
		3Y1O)					
WATER (UNII: 059QF0	KO0R)						
WATER (UNII: 059QF0 Product Characte	KOOR) Pristics		Score			nc	o score
	KOOR) eristics		Score Size				o score mm
WATER (UNII: 059QF0 Product Characte Color Shape	KOOR) eristics	YELLOW	Size	Code			mm
WATER (UNII: 059QF0 Product Characte Color Shape Flavor	KOOR) eristics	YELLOW		Code		61	mm
WATER (UNII: 059QF0 Product Characte Color	KOOR) eristics	YELLOW	Size	Code		61	mm
WATER (UNII: 059QF0 Product Characte Color Shape Flavor	KOOR) eristics	YELLOW	Size	Code		61	mm
WATER (UNII: 059QF0 Product Characte Color Shape Flavor Contains	KOOR) eristics	YELLOW	Size	Code		61	mm
WATER (UNII: 059QF0 Product Characte Color Shape Flavor Contains Packaging	KOOR) eristics	YELLOW ROUND	Size	Code	Marketing Start D	61 L	mm
WATER (UNII: 059QF0 Product Characte Color Shape Flavor Contains Packaging	KOOR) eristics	YELLOW ROUND Package	Size Imprint	Code	Marketing Start D 05/01/2011	61 L	mm
WATER (UNII: 059QF0 Product Characte Color Shape Flavor Contains Packaging I tem Code	ristics	YELLOW ROUND Package ARTON	Size Imprint		_	61 L	mm

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	0 5/0 1/20 11	

Labeler - Chain Drug Consortium (101668460)

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		038154464	PACK(68016-642)		

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		868734088	MANUFACTURE(68016-642), PACK(68016-642)		

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		967626305	PACK(68016-642)		

Revised: 5/2020

Chain Drug Consortium