

ASPIR LOW- aspirin tablet
Cardinal Health

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.

Drug Facts

Active ingredient

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Keep Out of Reach of Children

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Uses

- temporarily relieves minor aches and pains
- for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flulike 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

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

- you have not been drinking fluids
- you have lost a lot of fluid due to vomiting or diarrhea

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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear
- ringing in the ears or a loss of hearing occurs

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.

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

Inactive ingredients

anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C yellow #10 aluminum lake, iron oxide ochre, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

Questions?

Adverse Drug Event Call: (800) 616-2471

Other Information

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

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Compare to the active ingredient in **BAYER® Low Dose

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

Distributed by

Major Pharmaceuticals

31778 Enterprise Drive,

Livonia, MI 48150 USA

Rev. 02/13

Cardinal Health

Zanesville, OH 43701

IT49430641213

Principal Display Panel

ASPIR LOW TABLETS

LOW STRENGTH

81 mg ASPIRIN (NSAID)



Principal Display Panel

ASPIR LOW TABLETS

LOW STRENGTH

81 mg ASPIRIN (NSAID)

Enteric Coated

1¼ gr. (81 mg) each Analgesic

QTY 30

NDC 55154-5894-9 (CARDINAL HEALTH)

**ASPIR LOW TABLETS
LOW STRENGTH
81 mg ASPIRIN (NSAID)
Enteric Coated
1 1/4 gr. (81 mg) each Analgesic
QTY 30**



CUSTOMER ID

Active ingredient (in each tablet)
Aspirin 81 mg (NSAID)* (Pain reliever)
*nonsteroidal anti-inflammatory drug

Uses - temporarily relieves minor aches and pains - for other uses,
see your doctor, but do not use for more than 10 days without
consulting your doctor because serious side effects may occur
See product insert for prescribing information, precautions and warnings.

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

This package is intended for in-patient institutional use only.
Keep this and all drugs out of the reach of children.

MAJOR AND ASPIR LOW are trademarks owned by their respective owners.

Distributed by Major Pharmaceuticals
31778 Enterprise Drive,
Livonia, MI 48150 USA
Questions? (800) 616-2471

Repackaged By: Cardinal Health
Zanesville, OH 43701
LTB49430490114

Aspir Low Tablet
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ASPIR LOW
aspirin tablet

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55154-5894(NDC:0904-7704)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ASPIRIN (ASPIRIN)	ASPIRIN	81 mg

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS LACTOSE	
CARNAUBA WAX	
SILICON DIOXIDE	
CROSCARMELOSE SODIUM	
D&C YELLOW NO. 10	
FERRIC OXIDE YELLOW	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A	
CELLULOSE, MICROCRYSTALLINE	
POLYSORBATE 80	
DIMETHICONE	
SODIUM HYDROXIDE	
SODIUM LAURYL SULFATE	
TALC	
TITANIUM DIOXIDE	
TRIETHYL CITRATE	

Product Characteristics			
Color	YELLOW	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-5894-9	30 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	05/24/2011	

Labeler - Cardinal Health (188557102)

Establishment

Name	Address	ID/FEI	Business Operations
Cardinal Health		188557102	REPACK(55154-5894)

Revised: 3/2014

Cardinal Health