

ASPIRIN LOW- aspirin tablet
Unit Dose Services

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

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

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

Children and teenagers who have or are recovering from chicken pox or flu-like **Reye's syndrome:** 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.

Aspirin may cause a severe allergic reaction, which may include: **Allergy alert:**

- hives ■ facial swelling ■ shock ■ asthma (wheezing)

This product contains an NSAID, which may cause severe stomach **Stomach bleeding warning:** 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 ■ if you are allergic to aspirin or any other pain reliever/fever reducer **Do not use**

- stomach bleeding warning applies to you **Ask a doctor before use if**

- 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
- you experience any of the following signs of stomach bleeding: **Stop use and ask a doctor if**
- 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

, ask a health professional before use. It is especially important not **If pregnant or breast-feeding** 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

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

**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

ASPIR LOW™

LOW STRENGTH 81mg ASPIRIN (NSAID)

Enteric Coated

1 1/4 gr. (81 mg) each Analgesic

SEE NEW WARNINGS INFORMATION

NEW Tablet Appearance

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

MAJOR®

ASPIR LOW (ASPIRIN) TABLET

NDC:50436-0128-1

ASPIRIN EC 81MG 30 TABLETS

30 TABLETS, EACH CONTAINING
81MG ASPIRIN EC

LOT:XXXXX EXP:XXXXX

DIST BY: MAJOR PHARM
LIVONIA, MI 48150 USA

WARNING: KEEP OUT
OF REACH OF CHILDREN
STORE AT 25°C (77°F)
SEE PACKAGE INSERT FOR DOSAGE INFORMATION

MFG NDC:0904-7704-80

MFG LOT:XXXXX

PKG BY: UNIT DOSE SERVICES LLC, DANIA, FL



50436012801

ASPIR LOW

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50436-0128(NDC:49483-390)
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)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

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:50436-0128-1	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	05/24/2011	

Labeler - Unit Dose Services (831995316)

Registrant - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-0128)