

**ASPIR LOW- aspirin tablet**  
**Proficient Rx LP**

*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

\*\*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

**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®**

**Repackaged by:**

**Proficient Rx LP**



**Thousand Oaks, CA 91320**

**Package/Label Principal Display Panel**

Aspir Low

1 1/4 gr. (81 mg) (NSAID)

Enteric Coated Tablets

NDC 63187-913-72

Lot #:00000  
Exp. 00/00/00  
SN# MASTER

**Aspirin 81mg**  
#120 EC Tablets  
Lot #:00000 SN# MASTER  
NDC 63187-913-72 Exp:00/00/00

**Aspirin 81mg**  
#120 EC Tablets  
Lot #:00000 SN# MASTER  
NDC 63187-913-72 Exp:00/00/00

**Aspirin 81mg**  
#120 EC Tablets  
Lot #:00000 SN# MASTER  
NDC 63187-913-72 Exp:00/00/00

Each tablet contains: Aspirin 81 mg (NSAID\*) Pain reliever \*nonsteroidal anti-inflammatory drug

*Yellow, round, unscored tablet with a heart shape imprint.*

Product ID: RA091372  
Dist. By: Major Pharmaceuticals 31778 Enterprise Drive, Livonia, MI 48150 USA  
Store at 25°C (77°F) Keep medication out of the reach of children  
Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320

**ASPIR LOW**

aspirin tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63187-913(NDC:0904-7704)
<b>Route of Administration</b>	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: 3S Y5LH9 PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE 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)	
STARCH, CORN (UNII: O8232NY3SJ)	
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	HEART
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-913-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	
2	NDC:63187-913-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	
3	NDC:63187-913-72	120 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	

**Marketing Information**

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

**Labeler** - Proficient Rx LP (079196022)**Establishment**

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Proficient Rx LP		079196022	REPACK(63187-913) , RELABEL(63187-913)
------------------	--	-----------	--

Revised: 11/2019

Proficient Rx LP