LOW DOSE ASPIRIN- aspirin tablet, coated
Proficient Rx LP

481R-TCL-49483-481 ASPIRIN 81MG DELAYED RELEASE TABLETS

DRUG FACTS

Active ingredient (in each tablet)

Aspirin 81mg (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

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.
ask your doctor about other uses for enteric-coated 81 mg Aspirin

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 are age 60 or older

Have had stomach bleeding problems

Take a blood thinning (anticoagulant) or steroid drug

Take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen,

naproxen or others)

Directions

Drink a full glass of water with each dose

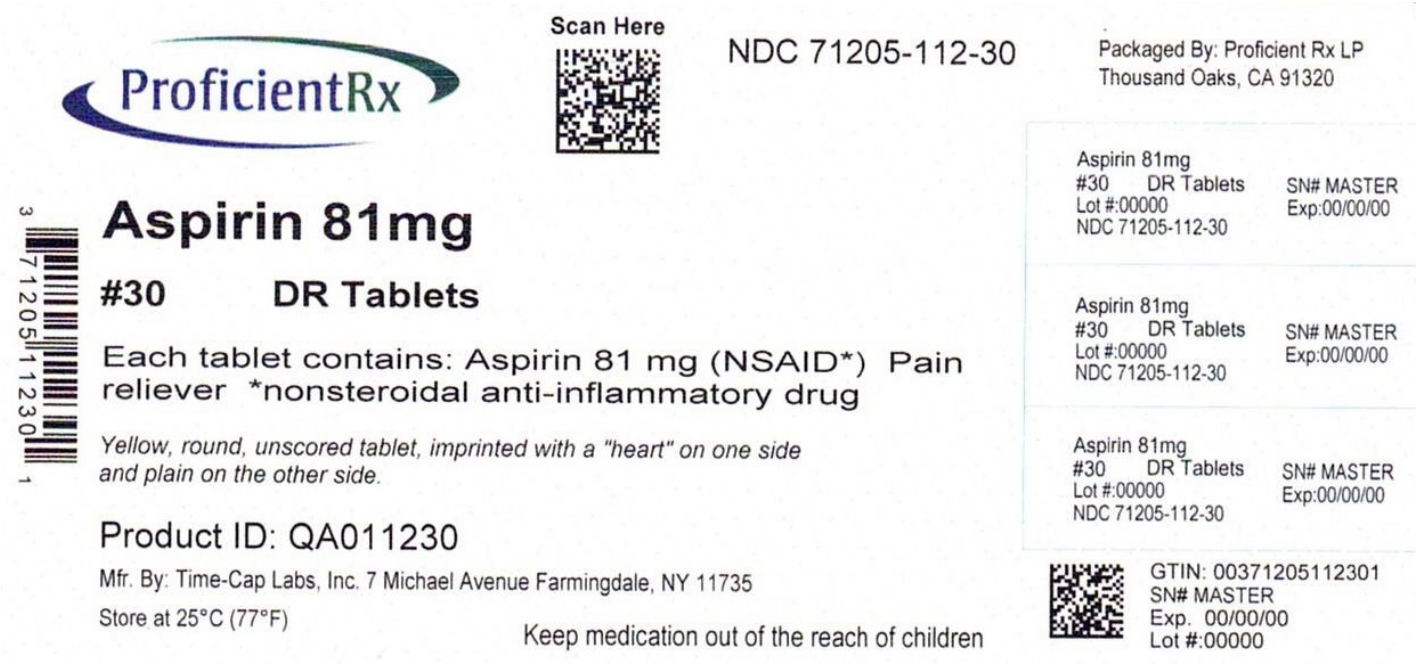
Adults and children of 12 years and over, take 4-8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor

Children under 12 years: consult a doctor

Inactive Ingredients

Anhydrous lactose, carnuba 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.

Package/Label Principal Display Panel



LOW DOSE ASPIRIN

aspirin tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71205-112(NDC:49483-481)
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
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:71205-112-10	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/04/2018	
2	NDC:71205-112-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/04/2018	
3	NDC:71205-112-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/04/2018	
4	NDC:71205-112-72	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/19/2015	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-112) , RELABEL(71205-112)

Revised: 12/2023