

LOW DOSE ASPIRIN- aspirin tablet, coated
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 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

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 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



NDC 71205-112-10

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

Aspirin 81mg

#10 DR Tablets

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

Yellow, round, Imprinted with a "heart" on one side and plain on the other side.

Product ID: QA011210

Mfr. By: Time-Cap Labs, Inc. 7 Michael Avenue Farmingdale, NY 11735
Store at 25°C (77°F)

Keep medication out of the reach of children

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Lot #00000 Exp:00/00/00
NDC 71205-112-10

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Aspirin 81mg
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NDC 71205-112-10

Packaged By: Proficient Rx LP
Thousand Oaks, CA 91320

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 - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (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	white	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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	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)