LOW DOSE ASPIRIN LOW DOSE- as pirin tablet, delayed release SMART SENSE (KMART)

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.

STS - 1146 - 2019-1008

Drug Facts

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID ¹)

1 nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

temporarily relieves minor aches and pains

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
- asthma (wheezing)
- shock

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 have ever had an allergic reaction to 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

Ask a doctor or pharmacist before use if you are taking a prescription drug for:

- gout
- diabetes
- arthritis

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- pain gets worse or lasts for more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious condition.

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.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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; do not exceed 48 tablets in 24 hours
- children under 12 years: do not use unless directed by a doctor

Other information

- store between 20°-25°C (68°-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

acetylated monoglycerides, anhydrous lactose, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C red #40, FD&C yellow #6, hypromellose, hypromellose phthalate, iron oxide yellow, methacrylic acid copolymer, microcrystalline cellulose, mineral oil, polyethylene glycol, polysorbate 80, simethicone, sodium hydroxide, sodium lauryl sulfate, talc, titanium dioxide, triethyl citrate

PRINCIPAL DISPLAY PANEL

Smart SenseTM

Compare to St. Joseph® Low Dose Aspirin†

Low Dose Aspirin

Pain Reliever (NSAID)

Safety-Coated

180 Tablets Enteric Coated

81 mg



COATING FREE AREA

LOW DOSE ASPIRIN LOW DOSE

aspirin tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49738-786
Route of Administration	ORAL		
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
DIACETYLATED MONO GLYCERIDES (UNII: 5Z17386USF)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)	
HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST) (UNII: 87Y6436BKR)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
MINERAL O IL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	orange (PEACH)	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	heart
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 ND 18	OC:49738-786-	1 in 1 CARTON	02/01/2013	
1		180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2 ND 36	OC:49738-786-	2 in 1 CARTON	07/01/2011	07/31/2019
2		180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	06/30/2011		

Labeler - SMART SENSE (KMART) (008965873)

Revised: 10/2019 SMART SENSE (KMART)