ASPIRIN CHEWABLE- as pirin 81 mg tablet A-S Medication Solutions

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/fever reducer

Uses

temporary relief of minor aches and pains or as recommended by your doctor to reduce fever

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 are allergic to aspirinor any other pain reliever/fever reducer this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

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 more than 10 days redness or swelling is present new symptoms occur ringing in the ears or loss of hearing occurs

You may report side effects to 1-888-952-0050

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 specifically 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 accidental overdose, get medical help or contact a PoisonControlCenter right away.

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

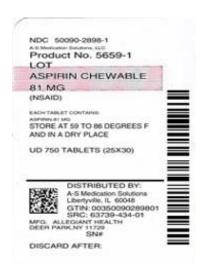
dextrates, FD&C yellow #6, flavor, saccharin sodium, starch

HOW SUPPLIED

Product: 50090-2898

NDC: 50090-2898-1 30 TABLET in a BLISTER PACK / 25 in a BOX, UNIT-DOSE

Aspirin 81 mg



ASPIRIN CHEWABLE

aspirin 81 mg tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-2898(NDC:69168-288)	
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			
DEXTRATES (UNII: G263MI44RU)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)				
STARCH, CORN (UNII: O8232NY3SJ)				

Product Characteristics				
Color	ORANGE	Score	no score	
Shape	ROUND	Size	7mm	
Flavor	ORANGE	Imprint Code	AZ013	
Contains				

ı	Packaging					
l	# Ite	n Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:50	090-2898-	25 in 1 BOX, UNIT-DOSE	03/03/2017		
	1		30 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	12/18/2014	

Labeler - A-S Medication Solutions (830016429)

Establishment				
Name	Address	ID/FEI	Business Operations	
A-S Medication Solutions		830016429	RELABEL(50090-2898)	

Revised: 5/2018 A-S Medication Solutions