

## **ASPIRIN CHEWABLE- aspirin 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.*

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### **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 aspirin or 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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-2898(NDC:69168-288)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
DEXTRATES (UNII: G263MI44RU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STARCH, CORN (UNII: O8232NY3SJ)	

**Product Characteristics**

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	AZ013
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-2898-1	25 in 1 BOX, UNIT-DOSE	03/03/2017	
1		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

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

**Labeler** - A-S Medication Solutions (830016429)**Establishment**

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