

CHEWABLE ASPIRIN- aspirin tablet, chewable
Genuine First Aid LLC

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.

Chewable Aspirin 81mg

Active Ingredient

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Analgesic/antipyretic

Uses

temporary relief of minor aches, pains and headaches

to reduce fever associated with colds, sore throats, teething

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.

Stomach bleeding warning: This product contains a non-steroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if the user; has had stomach ulcers or bleeding problems takes a blood thinning (anticoagulant) or steroid drug takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) takes more or for a longer time than directed is age 60 or older has 3 or more alcoholic drinks every while using this product.

Do not use

if you are allergic to aspirin or any other pain relievers/fever reducers

for more than 10 days for pain unless directed by a doctor

for more than 3 days for fever unless directed by a doctor

for at least 7 days after a tonsillectomy or oral surgery

Ask a doctor before use if you have:

asthma

stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, ulcers or bleeding problems

a child experiencing arthritis pain

if you are;

allergic to aspirin

taking prescription drug for anticoagulation (thinning of blood), diabetes, gout or arthritis

Stop use and ask a doctor if:

an allergic reaction occurs, Seek medical help right away

pain or fever persists

new or unexpected symptoms occur

redness or swelling is present

ringing in ears or loss of hearing occurs

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 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 immediately.

Directions

Do not use more than directed

Adults and Children (12 years and older): Chew 4 to 8 tablets with water every 4 hours, Do not exceed 48 tablets in 24 hours unless directed by a doctor.

Children Under 12 years: Consult a doctor.

Store at room temperature

tamper evident sealed packets

do not use any opened or torn packets

Inactive Ingredients

flavor, FD and C yellow No. 6, saccharin, sodium, silicon dioxide, starch, stearic acid, sucrose

MADE IN USA

Distributed by GENUINE FIRST AID

600 Cleveland Str Suite 400, Clearwater, FL 33755

2 Tablets

GENUINE FIRST AID.

Chewable Aspirin 81mg



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Active ingredient (in each tablet) Purpose

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Do not use ■ if you are allergic to aspirin or any other pain relievers/fever reducers ■ for more than 10 days for pain unless directed by a doctor ■ for more than 3 days for fever unless directed by a doctor ■ for at least 7 days after a tonsillectomy or oral surgery

Warnings (continued)

Ask a doctor before use if you have ■ asthma ■ stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, ulcers or bleeding problems ■ a child experiencing arthritis pain

if you are ■ allergic to aspirin ■ taking a prescription drug for anticoagulation (thinning of the blood), diabetes, gout or arthritis

Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away ■ pain or fever persists ■ new or unexpected symptoms occur ■ redness or swelling is present ■ ringing in the ears or loss of hearing occurs

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.**

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CHEWABLE ASPIRIN

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52124-0012
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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SACCHARIN (UNII: FST467XS7D)	
SODIUM CATION (UNII: LYR4M0NH37)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	orange (ORANGE)	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	ASPIRIN
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52124-0012-1	2 in 1 PACKAGE; Type 0: Not a Combination Product	04/02/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	04/02/2010	

Labeler - Genuine First Aid LLC (619609857)

Revised: 12/2019

Genuine First Aid LLC