ASPIRIN ADULT LOW STRENGTH- aspirin tablet, chewable Western Family Foods Inc

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.

Western Family Aspirin Drug Facts

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID)*

*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 pain reliever/fever reducer
- 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 have asthma
- you are taking a diuretic

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
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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 while symptoms persist.

Do not exceed 48 tablets in 24 hours or as directed by a doctor.

children under 12 do not use unless directed by a doctor

Other information

• store at 20°-25°C (68°-77°F)

Inactive ingredients

corn starch, dextrose excipient, FD&C yellow #6 aluminum lake, flavors, saccharin sodium

Principal Display Panel

Chewable

Pain Reliever (NSAID)

Aspirin

81 mg

Orange FLAVOR

ADULT Low Strength

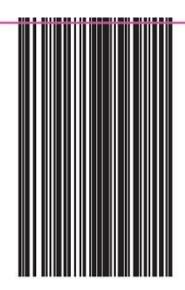
ORANGE FLAVOR

Actual Size

COMPARE TO ST. JOSEPH® active ingredient

Gluten Free





Drug Facts

Active ingredient (in each tablet)

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Purpose

Uses temporarily relieves minor aches and pains

Warnings

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- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

Drug Facts (continued)

- take a blood thinning (anticoagulant) or steroid drug
- 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 pain reliever/fever reducer

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 asthma
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic

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.

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 - feel faint vomit blood
 - have stomach pain that does not get better ■ have bloody or black stools
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days







ASPIRIN ADULT LOW STRENGTH

aspirin tablet, chewable

Pro	duct	Info	rma	tion
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Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:55312-259Route of AdministrationORALDEA Schedule

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
ASPIRIN (ASPIRIN) ASPIRIN 81 mg

Inactive Ingredients

mactive ingredients			
Ingredient Name	Strength		
SACCHARIN SO DIUM			
STARCH, CORN			

Product Characteristics

Color	ORANGE (Light Orange)	Score	no score
Shape	ROUND	Size	8 mm
Flavor	ORANGE	Imprint Code	L467
Contains			

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-259-68	1 in 1 CARTON		
1		36 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/18/2001	

Revised: 1/2013 Western Family Foods Inc