# HEALTHY ACCENTS ASPIRIN- as pirin tablet, chewable DZA Brands 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.

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### **DZA Brands, LLC Aspirin Drug Facts**

#### **Active ingredient (in each tablet)**

Aspirin 81 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

# Purpose

Pain reliever

#### Uses

for the temporary relief of 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
- for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

#### Ask a doctor before use if

- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic
- you have asthma

# Ask a doctor or pharmacist before use if you are

taking a prescription drug for diabetes, gout or 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
- fever gets worse or lasts for more than 3 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 not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

#### Other information

• store at 20-25°C (68-77°F)

# **Inactive ingredients**

corn starch, dextrose excipient, FD&C yellow no. 6 aluminum lake, flavors, saccharin sodium

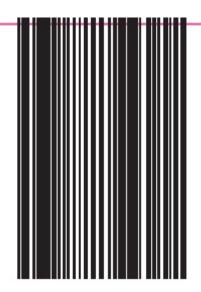
#### Questions or comments?

1-866-322-2439

# **Principal Display Panel**

Compare to Bayer® Chewable Aspirin active ingredient low dose aspirin pain reliever (NSAID) 81 mg low dose aspirin regimen orange flavor 81 mg each actual size





\*\*Aspirin is not appropriate for everyone, so be sure to talk to your doctor before you begin an aspirin regimen.

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Purpose

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# Drug Facts (continued)

- 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

for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

#### Ask a doctor before use if

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- you have a history of stomach problems, such as heartburn
- vou have high blood pressure, heart disease. liver cirrhosis, or kidney disease
- you are taking a diuretic you have asthma

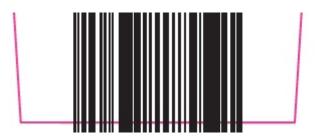
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- you experience any of the following signs of stomach bleeding:
  - feel faint
    vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better ▶







# **HEALTHY ACCENTS ASPIRIN**

aspirin tablet, chewable

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:55316-467

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)ASPIRIN81 mg

# Inactive Ingredients

inactive ingredicines			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			

### **Product Characteristics**

Color	ORANGE	Score	no score
Shape	ROUND	Size	8 mm
Flavor	ORANGE	Imprint Code	L467
Contains			

#### **Packaging**

# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1 NDC:55316-467-68	1 in 1 CARTON	02/04/2008	09/30/2020
1	36 in 1 BOTTLE; 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	02/04/2008	09/30/2020

# Labeler - DZA Brands LLC (090322194)

Revised: 12/2019 DZA Brands LLC