

**HEALTHY ACCENTS INFANTS PAIN AND FEVER- acetaminophen suspension**  
**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 Infants' Pain & Fever Drug Facts**

**Active ingredient (in each 5 mL)**

Acetaminophen 160 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

temporarily:

- reduces fever
- relieves minor aches and pains due to:
- the common cold
- flu
- headache
- sore throat
- toothache

**Warnings**

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child has ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if your child has**

liver disease

**Ask a doctor or pharmacist before use if your child is**

taking the blood thinning drug warfarin

**When using this product**

do not exceed recommended dose (see overdose warning)

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 5 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.

**Keep out of reach of children.**

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical even if you do not notice any signs or symptoms.

**Directions**

- this product does not contain directions or complete warnings for adult use
- do not give more than directed (see overdose warning)
- shake well before using
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Insert syringe tip into bottle opening.
- flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.
- pull yellow part of syringe until it reaches and stays at the correct dose
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- replace cap tightly to maintain child resistance

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL

\* or as directed by a doctor

Attention: use only enclosed syringe specifically designed for use with this product. Do not use any other dosing device.

## **Other information**

- store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing

## **Inactive ingredients**

anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

## **Questions or comments?**

1-866-322-2439

## **Package/Label Principal Display Panel**

PEDIATRICIAN PREFERRED DOSING SYSTEM

SEE NEW WARNINGS

infants'

pain & fever

acetaminophen

160mg per 5mL

pain reliever – fever reducer

suspension liquid

alcohol free – aspirin free

ibuprofen free – gluten free

for ages 2-3 years

Compare to Infants' Tylenol® Oral Suspension active ingredient

cherry flavor

2 FL OZ (59mL)

160mg per 5mL

USE ONLY WITH ENCLOSED SYRINGE

See side panel for more information



**PEDIATRICIAN  
PREFERRED  
DOSING SYSTEM**

NDC 55316-161-16  
**SEE NEW WARNINGS**

healthy accents<sup>®</sup>  
**infants'**  
**pain & fever**  
acetaminophen  
160mg per 5mL

pain reliever • fever reducer  
suspension liquid

alcohol free • aspirin free  
ibuprofen free • gluten free

for ages 2-3 years

Compare to Infants' Tylenol<sup>®</sup>  
Oral Suspension  
active ingredient



cherry flavor

**2 FL OZ (59mL)**  
160mg per 5mL

**USE ONLY WITH  
ENCLOSED SYRINGE**  
See side panel for more information



**IMPORTANT:**  
Please see dosing chart or ask a doctor for your child's correct dose.

**STEP 1.** See *Directions* for the correct dose for your child.

**STEP 2.** Shake well before using.

**STEP 3.** Push air out of syringe. Insert syringe tip into bottle opening.



**STEP 4.** Flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.

**STEP 5.** Pull yellow part of syringe until it reaches and stays at the correct dose.



**STEP 6.** Dispense liquid slowly into child's mouth.

pain reliever • fever reducer

acetaminophen 160mg per 5mL

**infants'**

healthy accents<sup>®</sup>

**Drug Facts**

**Active ingredient (in each 5 mL)**      **Purpose**

Acetaminophen 160 mg.....Pain reliever/fever reducer

**Uses** temporarily:      ■ reduces fever  
 ■ relieves minor aches and pains due to:      ■ the common cold  
 ■ flu      ■ headache      ■ sore throat      ■ toothache

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes more than 5 doses in 24 hours, which is the maximum daily amount with other drugs containing acetaminophen.

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening      ■ blisters      ■ rash. If a skin reaction occurs, stop use and seek medical help right away.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Do not use**      ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.  
 ■ if your child has ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if your child has liver disease**

**Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin**

**When using this product do not exceed recommended dose (see overdose warning)**

**Stop use and ask a doctor if**  
 ■ pain gets worse or lasts more than 5 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.

**Keep out of reach of children.**

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**Directions**

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**Drug Facts (continued)**

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**Inactive ingredients** anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, FD&C red #40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

**Questions or comments?**  
1-866-322-2439



DISTRIBUTED BY: DZA BRANDS, LLC  
 Salisbury, NC 28147 / Scarborough, ME 04074  
 For product questions or concerns, contact us at 1-866-322-2439. Please include UPC number and code from package.

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LOT NO.

EXP.

: 16116 HA C4

<b>HEALTHY ACCENTS INFANTS PAIN AND FEVER</b>			
acetaminophen suspension			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55316-161
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL	

## Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYL PARABEN (UNII: 3QP1U3FV8)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	

## Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-161-16	1 in 1 CARTON	12/06/2011	
1		59 mL 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	12/06/2011	

**Labeler** - DZA Brands LLC (090322194)

Revised: 12/2018

DZA Brands LLC