# HEALTHY ACCENTS PAIN RELIEF- 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 Children's Pain Relief Drug Facts

# Active ingredient (in each 5 mL = 1 teas poonful)

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

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

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: Taking more than the recommended dose (overdose) may cause liver damage. 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; tsp = teaspoonful
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (mL or tsp)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL (1 tsp)
36-47	4-5 years	7.5 mL (1 ½ tsp)
48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2 ½ tsp)
72-95	11 years	15 mL (3 tsp)

<sup>\*</sup>or as directed by a doctor

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

# Other information

- each 5 mL (1 tsp) contains: sodium 3 mg
- 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, D&C red #33, FD&C blue #1, 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

# **Principal Display Panel**

children's pain relief
acetaminophen
fever reducer - pain reliever
oral suspension
for ages 2 - 11
Compare to Children's Tylenol® Oral Suspension active ingredient
grape flavor
4 FL OZ (118mL)
160mg per 5mL
alcohol free
gluten free









# **Drug Facts**

Active ingredient

Purpose

(in each 5 mL = 1 teaspoonful)
Acetaminophen 160 mg...Pain reliever/fever reduce

- 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

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- Do not use

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  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 warm

### 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.

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(1-800-222-1222) Quick medical attention is critical even if you do not notice any signs or symptoms.

### Drug Facts (continued)

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Inactive ingredients anhydrous citric acid, butylparaben, calcium sulfate, carrageenan, D&C red #33, FD&C blue #1,

carrageenan, DAC red #33, FDAC DIUE #1, flavor, glycenin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylicellulose 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.





NDC 55316-130-26

# Children's

# acetaminophen

fever reducer • pain reliever oral suspension

for ages 2 - 11

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Compare to Children's Tylenol® Oral Suspension active ingredient



4 FL OZ (118mL) 160mg per 5mL alcohol free • gluten free



# Children's

# acetaminophen

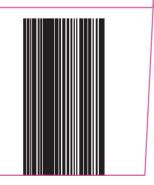
fever reducer • pain reliever oral suspension

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4 FL OZ (118mL) 160mg per 5mL alcohol free • gluten free





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# **HEALTHY ACCENTS PAIN RELIEF**

acetaminophen suspension

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55316-130
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	160 mg in 5 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDRO US CITRIC ACID			
BUTYLPARABEN			
CARBOXYMETHYLCELLULOSE SODIUM			
CARRAGEENAN			
D&C RED NO. 33			
FD&C BLUE NO. 1			
GLYCERIN			
HIGH FRUCTO SE CORN SYRUP			
CELLULOSE, MICRO CRYSTALLINE			
PROPYLENE GLYCOL			
WATER			
SO DIUM BENZO ATE			
SORBITOL			
CALCIUM SULFATE			
SO DIUM PHO SPHATE, TRIBASIC			

Product Characteristics			
Color	PURPLE (viscous)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-130-26	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/06/2011	

# Labeler - DZA Brands LLC (090322194)

Revised: 11/2013 DZA Brands LLC