PAIN RELIEF- acetaminophen suspension
Publix Super Markets 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.

Publix Super Markets, Inc. Pain Relief 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 bottle wrap 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

Package/Label Principal Display Panel

FOR AGES 2-3 YEARS

INFANTS'

pain relief

ACETAMINOPHEN 160 mg PER 5 mL

PAIN RELIEVER/FEVER REDUCER

SUSPENSION LIQUID

Ibuprofen free

Alcohol free

Aspirin free

CHERRY FLAVOR

PEDIATRICIAN PREFERRED DOSING SYSTEM

USE ONLY WITH ENCLOSED SYRINGE.

SEE SIDE PANEL FOR MORE INFORMATION.

1 FL OZ (30 mL)

Compare to Infants' Tylenol® Oral Suspension active ingredient

PAIN RELIEF

acetaminophen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56062-161
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

BUTYLPARABEN (UNII: 3QPI1U3FV8)	
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:56062-161-10	1 in 1 CARTON	11/29/2011	
1		30 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	11/29/2011	

Labeler - Publix Super Markets Inc (006922009)

Revised: 10/2018 Publix Super Markets Inc