

**CHILDRENS ACETAMINOPHEN- acetaminophen suspension**  
**Padagis Israel Pharmaceuticals Ltd**

*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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**Perrigo Children's Acetaminophen 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 below. 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)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL

36-47	4-5 years	7.5 mL
48-59	6-8 years	10 mL
60-71	9-10 years	12.5 mL
72-95	11 years	15 mL

\*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 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, 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?

**1-800-719-9260**

### Principal Display Panel

Compare to Children's Tylenol® Oral Suspension active ingredient

Children's Acetaminophen

160 mg per 5 mL

Pain Reliever-Fever Reducer

Oral Suspension

For Ages 2 to 11 Years

Aspirin Free

Ibuprofen Free

Alcohol Free

Dosage Cup Included

Cherry Flavor

4 FL OZ (118 mL)

Compare to Children's Tylenol®  
Oral Suspension  
active ingredient

**Perrigo®**

NDC 45802-203-26

**Children's  
Acetaminophen**  
**160 mg per 5 mL**

Pain Reliever-Fever Reducer  
**Oral Suspension**

- ✓ For Ages 2 to 11 Years
- ✓ Aspirin Free
- ✓ Ibuprofen Free
- ✓ Alcohol Free



**Cherry  
Flavor**



Dosing Cup  
Included

**4 FL OZ (118 mL)**

NDC 45802-203-26

**Children's  
Acetaminophen**  
**160 mg per 5 mL**  
Pain Reliever-Fever Reducer  
**Oral Suspension**

**DIRECTIONS:**

**STEP 1.**  
Shake well  
before using



**STEP 2.**  
Remove child  
protective  
cap



**STEP 3.**  
Squeeze your  
child's dose  
into the  
dosing cup



**IMPORTANT:**

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

**Cherry Flavor**  
**Oral Suspension**  
Pain Reliever-Fever Reducer  
**160 mg per 5 mL**  
**Children's  
Acetaminophen**  
NDC 45802-203-26

**Drug Facts**

**Active ingredient** *Purpose*  
(in each 5 mL)  
Acetaminophen 160 mg.....Pain reliever/fever reducer

**Uses temporarily:**

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  - flu
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  - sore throat
  - toothache

**Warnings**

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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 warning)**

**Stop use and ask a doctor if**

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- 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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**Drug Facts (continued)**

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**Inactive ingredients**

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**Questions or comments?**  
1-800-719-9260

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**CHILDRENS ACETAMINOPHEN**

acetaminophen suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45802-203
<b>Route of Administration</b>	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, UNSPECIFIED FORM (UNII: WAT0DDB505)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (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 (opaque)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-203-26	1 in 1 CARTON	04/09/2014	
1		118 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	04/09/2014	

**Labeler** - Padagis Israel Pharmaceuticals Ltd (600093611)

