

BABIES R US CHILDRENS PAIN RELIEF- acetaminophen suspension

Toys "R"Us, 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.

Toys "R" Us, Inc. Children's Pain Relief Drug Facts

Active ingredient (in each 5 mL = 1 teaspoon)

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

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.

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 Liver warning)
- shake well before using
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

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

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

Other information

- each teaspoon 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?

1-800-719-9260

Principal Display Panel

For Ages 2 - 11

Children's Pain Relief

Acetaminophen

Oral Suspension Liquid

Fever Reducer – Pain Reliever

Aspirin Free

Ibuprofen Free

Alcohol Free

Grape Flavor

Compare to active ingredient of Children's Tylenol® Oral Suspension

80 mg per 1/2 teaspoon (160 mg per 5 ml)

For Ages 2 - 11

Children's Pain Relief

Acetaminophen

Oral Suspension Liquid
Fever Reducer - Pain Reliever

NDC 51334-130-26

BABIES  US[®]

For Ages 2 - 11

Children's Pain Relief

Acetaminophen

Oral Suspension Liquid
Fever Reducer - Pain Reliever

Aspirin Free
Ibuprofen Free
Alcohol Free

**Grape
Flavor**



For Ages 2 - 11

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Acetaminophen

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Aspirin Free
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**Grape
Flavor**



NDC 51334-130-26

BABIES  US[®]



Compare to active ingredient of
Children's Tylenol® Oral Suspension*

4 fl oz (118 ml)

80 mg per 1/2 teaspoon (160 mg per 5 ml)

3920069H10



LOT NO.

EXP.

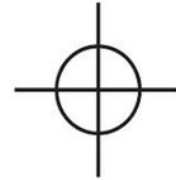
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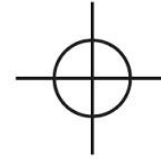
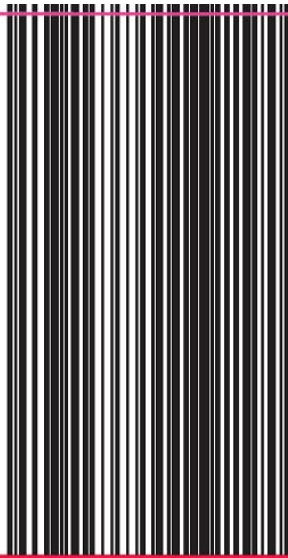


Compare to active ingredient of
Children's Tylenol® Oral Suspension*

4 fl oz (118 ml)

80 mg per 1/2 teaspoon (160 mg per 5 ml)





Drug Facts

Active ingredient Purpose (in each 5 mL = 1 teaspoon)

Acetaminophen 160 mg...Pain reliever/fever reducer

Uses temporarily:

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- relieves minor aches and pains due to:
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Stop use and ask a doctor if

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Drug Facts (continued)

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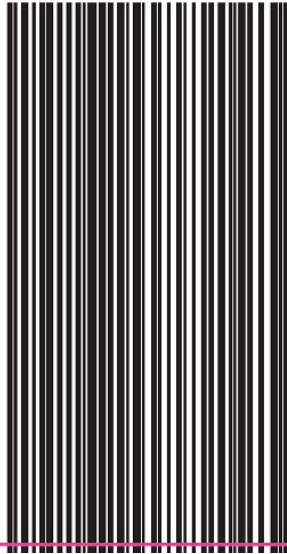
Questions or comments?

1-800-719-9260

www.babiesrus.com

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 *This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.



BABIES R US CHILDRENS PAIN RELIEF

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51334-130
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
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

SORBITOL (UNII: 506T60A25R)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	

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:51334-130-26	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	12/01/2010	

Labeler - Toys"R"Us, Inc. (006985808)

Revised: 1/2013

Toys"R"Us, Inc.