

CHILDRENS PAIN AND FEVER- acetaminophen liquid

Discount Drug Mart

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.

Children's Pain & Fever 526

Drug Facts

Active ingredient

(in each 5 mL = 1 teaspoonful)

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 a 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 is allergic to acetaminophen or to any of the inactive ingredients in this product

Ask a doctor 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 warnings)

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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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 for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult use.
- shake well before using
- mL = milliliter; tsp = teaspoonful
- find right dose on chart below. If possible, use weight to dose, otherwise, use age.
- if needed, repeat dose every 4 hours while symptoms last
- do not give for more than 5 days unless directed by a doctor

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 1/2 tsp)
48-59	6-8 years	10 mL (2 tsp)
60-71	9-10 years	12.5 mL (2 1/2 tsp)
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 5mL (1 tsp) contains sodium 3mg
- store between 20-25

Inactive ingredients

anhydrous citric acid, butylparaben, D&C Red # 33, FD&C (red), flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Questions

Call weekdays from 9:30 AM to 4:30 PM

Children's Pain & Fever product label

DISCOUNT

drug mart

FOOD FAIR

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S TYLENOL® ORAL SUSPENSION

Fever Reducer / Pain Reliever

Children's Pain & Fever

Acetaminophen Oral Suspension

- Alcohol-Free
- Ibuprofen Free
- Aspirin Free

For Ages 2 to 11

GRAPE FLAVOR

4 FL OZ (118 mL)

160 mg per 5 mL

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

BX-053

SATISFACTION GUARANTEED

IF DISSATISFIED, RETURN THE UNUSED PORTION AND PACKAGE TO STORE WHERE PURCHASED. IF UNABLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS, AND EMPTY PACKAGE TO: DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHIO 44256

DO NOT USE IF PRINTED NECK BAND IS BROKEN OR MISSING

Drug Facts

Active ingredient **Purpose**
(in each 5 mL = 1 teaspoonful)
Acetaminophen 160 mg.....Pain reliever/fever reducer

Uses temporarily ■ reduces fever
■ relieves minor aches and pains due to:
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■ headache
■ sore throat ■ toothache

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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 is allergic to acetaminophen or any of the inactive ingredients in this product
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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Drug Facts (continued)

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■ each 5 mL (1 tsp) contains: sodium 3 mg
■ store between 20-25°C (68-77°F)
■ do not refrigerate
■ Keep carton for full directions for use.

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Questions? Call weekdays from 9:30 AM to 4:30 PM EST at 1-877-798-5944

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COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S TYLENOL® ORAL SUSPENSION*

Fever Reducer / Pain Reliever

Children's Pain & Fever

Acetaminophen Oral Suspension

- Alcohol-Free
 - Ibuprofen Free
 - Aspirin Free
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8X-053

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CHILDRENS PAIN AND FEVER

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-526
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)	
BUTYL PARABEN (UNII: 3QP11U3FV8)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	grape	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-526-24	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/04/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/04/2016	

Labeler - Discount Drug Mart (047741335)

Registrant - Aptapharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
Aptapharma Inc.		790523323	manufacture(53943-526)