CHILDRENS PAIN AND FEVER, GRAPE FLAVOR- acetaminophen suspension Walgreen Company

Childrens Pain & Fever, Grape flavor

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 nyour 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 ever, 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.
- \blacksquare If your child is allergic to acetaminophen or any other 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

■ pain gets worse or lasts more than 5 days
 ■ fever gets worse or lasts more than 3 days
 ■ new symptoms
 ■ 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 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 the right dose on the chart below. If possible, use weight to dose, otherwise, use age.
- 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 (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 (3 tsp)

^{*}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 between 20-25°C (68-77°F)
- do not refrigerate
- **■** Keep carton for full directions for use.

Inactive ingredients Anhydrous citric acid, butylparaben, D&C Red #33 FD&C Blue #1, 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 EST at **1-877-798-5944**

Product Label

Walgreens

Compare to Children's Tylenol® Oral Suspension active ingredien^{t††}

NDC 0363-0323-24

children's

Pain & Fever

ACETAMINOPHEN 160 mg PER 5 mL

PAIN RELIEVER /
FEVER REDUCER
ORAL SUSPENSION

ALCOHOL FREE ASPIRIN FREE IBUPROFEN FREE

AGES 2-11 YEARS

GRAPE FLAVOR

4 FL OZ (118 mL)

This product is bot manufactured or distributed by Johnson & Johnson Consumer Inc., |McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.

ITEM 268955 W00000-0

REV-1020

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Walgreens Pharmacist Recommended Walgreens Pharmacist Survey

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DOSAGE CUP PROVIDED BX-114

ORG1020-F

Carton



Bottle



DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Active ingredient (in each 5 mL = 1 teaspoonful) Acetaminophen 160 mg.

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: acelaminophen 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 a pharmacist. **II** 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 ■ pain gets worse or lasts more than 5 days I fever gets worse or lasts more than 3 days I 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 for adults as well as for children even if you do not notice any signs or symptoms Directions I 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 more than 5 times in 24 hours do not give for more than 5 days unless directed by a doctor.

Age (yr)	Dose (mL or tsp)* ask a doctor	
under 2 years		
2-3 years	5 mL (1 tsp)	
4-5 years	7.5 ml. (1½ tsp)	
6-8 years	10 mL (2 tsp)	
9-10 years	12.5 mL (2½ tsp)	
11 years	15 mL (3 tsp)	
	under 2 years 2-3 years 4-5 years 6-8 years 9-10 years	

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 between 20-25°C (68-77°F)

do not refrigerate Inactive Ingredients: anhydrous citric acid, butylparaben, D&C Red # 33, FD&C Blue # 1, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum.

Questions? Call 1-877-798-5944

This product is not manufactured or distributed by Johnson
6 Johnson Consumer Inc. I McNeil Consumer Healthcare,

distributor of Children's Tylenol* Oral Suspension

DISTRIBUTED BY: WALGREEN CO. ITEM 268955 200 WILMOT RD., DEERFIELD, IL 60015

W00000-0000-0 LR-154 EXP:

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CHILDRENS PAIN AND FEVER, GRAPE FLAVOR

acetaminophen suspension

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-0323

Route of Administration ORAL

XANTHAN GUM (UNII: TTV12P4NEE)

Active Ingredient/Active Moiety

Ingredient Name

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)

Basis of Strength

ACETAMINOPHEN

ACETAMINOPHEN

160 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
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)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	purple	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0363-0323- 24	1 in 1 CARTON	11/05/2020		
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 Drug	M013	11/05/2020	

Labeler - Walgreen Company (008965063)

Registrant - AptaPharma Inc. (790523323)

Establishment				
Na me	Address	ID/FEI	Business Operations	
AptaPharma Inc.		790523323	manufacture(0363-0323)	

Revised: 12/2023 Walgreen Company