CHILDRENS PAIN AND FEVER- acetaminophen suspension Walgreen Company

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.

Walgreen Co. Children's Pain & Fever 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, 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

Walgreens

WALGREENS PHARMACIST RECOMMENDED

Compare to the active ingredient in Children's Tylenol® Oral Suspension

children's Pain & Fever

ACETAMINOPHEN 160 mg PER 5 mL

PAIN RELIEVER / FEVER REDUCER

ORAL SUSPENSION

Aspirin Free

Alcohol Free

Ibuprofen Free

AGES 2-11 YEARS

4 FL OZ (118 mL)

Grape flavor





Pain & Fever

Children's

ACETAMINOPHEN 160 mg PER 5 mL

PAIN RELIEVER / FEVER REDUCER

Drug Facts

Active ingredient

Purpose

(in each 5 mL)

- Uses temporarily:

 I reduces fever
 I releves minor aches and pains due to:

 If the common cold

 The I headsche

 one throat

 I tothache

Warnings

war immys
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 maximu

- dally amount other drugs containing a cetaminophen
 Allergy alert. Acetaminophen may cause severe skin
 reactions. Symptoms may include:

 skin reddoming

 tis skin reaction occurs, stop use and seek medical help

 ff a skin reaction occurs, stop use and seek medical help

If a bint resource in register is one throat is severe, persists Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fewer, headache, rash, nausea, or vorniting, 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 preminacion. 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 recommo

- Stop use and ask a doctor if
 poin 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 en if you do not notice any signs or symptoms.

Drug Facts (continued)

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 = milliter
- find right dose on chart below. If possible, use weight
- min right cose of near below. It positive, 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

]	to not give more than 5 times in 24 nours			
	Weight (lb)	Age (yr)	Dose (mL)*	
	under 24	under 2 years	ask a doctor	
Ī	24-35	2-3 years	5 mL	
Ī	36-47	4-5 years	7.5 mL	
	48-59	6-8 years	10 mL	
Ī	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

IMACTURE INGREDIENTS
anhydrous cirits acid, butyparaben, calcium sulfate,
carrageenan, D&C red #33, FD&C blue #1, favor,
glycein, high fructose con syrur, hydroxyethyl cellulose,
microcrystalline cellulose and carboxymethylcellulose
sodkum, propylene glycol, purified water, sodium
benzoate, sorbitol solution, tribasic sodium phosphate

Questions or comments?



DOSAGE CUP PROVIDED

Gluten Free



Compare to the active ingredient in Children's Tylenol® Oral Suspension

Pain &

Fever

ORAL SUSPENSION

Aspirin Free

Alcohol Free

AGES 2-11

YEARS

4 FL 0Z (118 mL)

Ibuprofen Free

DIRECTIONS: Shake well before using



STEP 2. Remove child protective cap



STEP 3. Squeeze your child's dose dosing cup



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





DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015 100% SATISFACTION GUARANTEED walgreens.com ©2021 Walgreen Co.



13026 94 C17

CHILDRENS PAIN AND FEVER

acetaminophen suspension

Product Information

Product Type HUMAN OTC DRUG **Route of Administration ORAL**

Item Code (Source)

NDC:0363-0212

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	160 mg in 5 mL	

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CALCIUM SULFATE, UNSPECIFIED FORM (UNII: WATODDB505)	
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)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	

Product Characteristics			
Color	PURPLE (viscous)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0212- 26	1 in 1 CARTON	07/31/1998	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0212- 28	1 in 1 CARTON	08/22/2013	12/31/2020
2		148 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363-0212- 34	2 in 1 CARTON	11/13/2014	
3		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	10/13/1995	

Labeler - Walgreen Company (008965063)

Revised: 3/2023 Walgreen Company