

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. Infants' 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. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Insert syringe tip into bottle opening.
- flip bottle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.
- pull yellow part of syringe until it reaches and stays at the correct dose
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- replace cap tightly to maintain child resistance

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL

* or as directed by a doctor

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

Other information

- 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

Package/Label Principal Display Panel

Walgreens

WALGREENS PHARMACIST RECOMMENDED

Compare to the active ingredient in infants' Tylenol®

Infants' Pain & Fever

ACETAMINOPHEN 160 mg PER 5 mL ORAL SUSPENSION

PAIN RELIEVER / FEVER REDUCER

Alcohol Free

Aspirin Free

Ibuprofen Free

AGES 2-3 YEARS

Cherry flavor

USE ONLY ENCLOSED SYRINGE.

See label booklet for more information.

2 FL OZ (60 mL)

Drug Facts (continued)

- pull yellow part of syringe until it reaches and stays at the correct dose
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- replace cap tightly to maintain child resistance

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL) ^a
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL

^a or as directed by a doctor

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

Other information

- store at 20-25°C (68-77°F)
- do not use if printed neckband is broken or missing

Inactive ingredients: anhydrous citric acid, calcium sulfite, carboxymethylcellulose, FD&C red #40, flavor glycerin, high fructose corn syrup, hydroxyethylcellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, tribasic sodium phosphate

Questions or comments? 1-800-719-9260

Información sobre el fármaco (continuación)

- presenta enrojecimiento o hinchazón. Estos signos podrían indicar una alergia grave.

Mantener fuera del alcance de los niños.

Advertencia de sobredosis: En caso de sobredosis, busque asistencia médica o contáctese inmediatamente con el Centro de Control Tóxico (1-800-222-1222). Es fundamental la atención médica urgente incluso si no detecta signos o síntomas.

Instrucciones

- este producto no contiene instrucciones o advertencias completas para uso en adultos
- no administrar más de lo indicado (ver advertencia de sobredosis)
- agite bien antes de usar
- 1 mL = mililitro
- encuentre la dosis adecuada en la tabla. Si es posible, use el peso para calcular la dosis; de lo contrario, use la edad.
- elimine el aire de la jeringa. Inserte la punta de la jeringa en la boca del frasco.
- gire el frasco hacia abajo. Tire de la parte amarilla de la jeringa hasta la línea de la primera dosis y luego coloque el producto nuevamente en el frasco.
- tire de la parte amarilla de la jeringa hasta que alcance y permanezca en la dosis correcta
- dispense el líquido lentamente en la boca del niño hacia la mejilla interna
- repita la dosis cada 4 horas mientras permanezcan los síntomas
- no administre la dosis más de 5 veces en 24 horas
- vuelva a colocar la tapa firmemente para que siga siendo resistente a los niños

Tabla de administración de la dosis

Peso (lb)	Edad (años)	Dosis (mL) ^a
menos de 24	menos de 2 años	consulte con su médico
24-35	2-3 años	5 mL

^a o según se lo indique su médico

Atención: use solamente la jeringa adjunta específicamente diseñada para ser usada con este producto. No use ningún otro dispositivo de administración de dosis.

Otra información

- almacene entre 20 y 25 °C (68 y 77 °F)
- no usar si no tiene precinto impreso o si este está roto

Ingredientes inactivos: ácido cítrico anhidro, sulfato de calcio, carboximetilcelulosa, goma 40 FD&C, saborizante, gliceras, jarabe de maíz alto en fructosa, hidroxietilcelulosa, celulosa microcristalina y carboximetilcelulosa sódica, propilenglicol, agua purificada, benzoato de sodio, solución de sorbitol, fosfato sódico tribásico

Preguntas o comentarios? 1-800-719-9260

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Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.

¹ This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Infants' Tylenol®.

² Este producto no es fabricado ni distribuido por Johnson & Johnson Consumer Inc., el distribuidor de Infants' Tylenol®.

NDC 0363-0161-94

Walgreens

Compare to the active ingredient in Infants' Tylenol®^{1,2}

Comparación con el ingrediente activo de Infants' Tylenol®^{1,2}

Infants' Pain & Fever Dolor & Fiebre en Bebés

ACETAMINOPHEN 160 mg PER 5 mL ORAL SUSPENSION
ACETAMINOFEN 160 mg POR CADA 5 mL SUSPENSIÓN ORAL

PAIN RELIEVER / FEVER REDUCER
PARA ALIVIA EL DOLOR / REDUCIR LA FIEBRE

Alcohol Free
Libre de alcohol

Aspirin Free
Sin aspirina

Ibuprofen Free
Sin ibuprofeno

Paraben Free
Sin parabenos

AGES 2-3 YEARS

Para 2 a 3 años de edad

2 FL OZ (60 mL)

Cherry flavor
sabor a Cereza

USE ONLY ENCLOSED SYRINGE.
See label booklet for more information.
Use únicamente la jeringa adjunta.
Vea el prospecto para obtener más información.

Drug Facts

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

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

Warnings

Liver warnings: 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 redness, hives, 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 non-prescription).
- 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.

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PAIN AND FEVER

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0161
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)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CALCIUM SULFATE, UNSPECIFIED FORM (UNII: WAT0DDDB505)	
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	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0161-10	1 in 1 CARTON	09/16/2011	05/31/2021
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0161-16	1 in 1 CARTON	12/02/2011	08/28/2019
2		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363-0161-94	1 in 1 CARTON	08/25/2017	
3		60 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	09/16/2011	

Labeler - Walgreen Company (008965063)

Revised: 3/2023

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