

**PAIN AND FEVER- acetaminophen suspension**  
**Walgreen Company**

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**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**

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
under 24	under 2 years	ask a doctor

24-35	2-3 years	5 mL
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\* 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

Weight (lb)	Age (yr)	Dose (mL) <sup>a</sup>
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, calcium sulfite, carageenan, 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?** 1-800-719-9280

**Información sobre el fármaco**  
**Ingrediente activo (en cada 5 ml)** **Indicaciones**  
 Acetaminofén 160 mg. Para aliviar el dolor/reducir la fiebre

**Usos temporales:** ■ disminuye la fiebre ■ alivia molestias y dolores leves causados por: ■ resfriado común ■ gripe ■ dolor de cabeza ■ dolor de garganta ■ dolor de muelas

**Advertencias**  
**Advertencia hepática:** Este producto contiene acetaminofén. Puede ocurrir daño hepático grave si su hijo/a toma ■ más de 5 dosis en 24 horas, que es la cantidad diaria máxima permitida ■ con otros fármacos que contienen acetaminofén.  
**Alerta sobre alergia:** El acetaminofén puede causar reacciones cutáneas graves. Entre los síntomas se podrían presentar: ■ enrojecimiento de la piel ■ ampollas ■ exantema. Si se produce una reacción cutánea, deje de tomar el fármaco y acuda a un médico de inmediato.  
**Advertencia sobre el dolor de garganta:** Si el dolor de garganta es grave, persiste por más de 2 días, está acompañado de fiebre o se postoriar a esta, dolor de cabeza, exantema, náuseas o vómitos, consulte a un médico de inmediato.

**No tomar** ■ con cualquier otro fármaco que contenga acetaminofén (con o sin receta). Si no está seguro de que un fármaco contenga acetaminofén o no, consulte con un médico o farmacéutico. ■ si su hijo/a alguna vez ha presentado una reacción alérgica a este producto o a cualquiera de sus ingredientes.  
**Consulte con un médico antes de tomarlo si su hijo/a tiene enfermedad hepática.**  
**Consulte con un médico o farmacéutico antes de tomarlo si su hijo/a está tomando el fármaco anticoagulante warfarina.**

**Al usar este producto, no exceda la dosis recomendada (vea la advertencia de sobredosis)**  
 Deje de tomarlo y consulte con un médico si ■ el dolor empeora o dura más de 5 días ■ la fiebre empeora o dura más de 3 días ■ ocurren nuevos síntomas

**Información sobre el fármaco (continuación)**  
 ■ presenta enrojecimiento o hinchazón. Estos signos podrían indicar una afección grave.  
**Mantener fuera del alcance de los niños.**  
**Advertencia de sobredosis:** En caso de sobredosis, busque asistencia médica o contacte inmediatamente con el Centro de Control Toxicológico (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 ■ 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) <sup>a</sup>
menos de 24	menos de 2 años	consulte con su médico
24-35	2-3 años	5 ml

<sup>a</sup> 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, carageenano, rojo 40 FD&C, saborizante, glicirina, 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?** 1-800-719-9280

**Walgreens** 

<sup>1</sup>Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.  
<sup>2</sup>This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Infants' Tylenol®.  
<sup>3</sup>Este producto no es fabricado ni distribuido por Johnson & Johnson Consumer Inc., el distribuidor de Infants' Tylenol®.

**Walgreens** 

Compare to the active ingredient in Infants' Tylenol®<sup>4†</sup>  
 Comparación con el ingrediente activo de Infants' Tylenol®<sup>4†</sup>

# Infants' Pain & Fever Dolor & Fiebre en Bebés

ACETAMINOPHEN 160 mg PER 5 mL ORAL SUSPENSION  
 ACETAMINOFEN 160 mg POR CADA 5 ml SUSPENSION 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.



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ITEM 341462 W10106-0223-L



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**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: ■ 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 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 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.



PAPER BOX PLASTIC BOTTLE PLASTIC SYRINGE

## 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
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
<b>CALCIUM SULFATE, UNSPECIFIED FORM</b> (UNII: WAT0DDB505)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SODIUM PHOSPHATE, TRIBASIC</b> (UNII: A752Q30A6X)	

## Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## 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	08/31/2025
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 Drug	M013	09/16/2011	08/31/2025

**Labeler** - Walgreen Company (008965063)

