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.



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 docto	(

Attention: use only enclosed syrings 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 missi

Inactive ingredients anlydrous ciric acid, calciun sulfate, carrageenan, FD&T ed 440, flwog glycerin, high fructuse com synup, hydrogethyl calulose, micro crystaline calulose and carbosynethyl cellulose sodium, propylene glycol, purified water, sodium beroostie, sodráld solution, tribasic sodium phosphate Questions or comments? 1-800-719-9260

Información sobre el fármaco

Indicaciones Ingrediente activo (en cada 5 ml) .Para aliviar el dolon/reducir la fieb

Usos temporalmente: ■ disminuye la fiebre ■ alivia molesfasy dolores leves causados por: ■ restifio común ■ gripe ■ dolor de cabeza ■ dolor de garganta ■ dolor de muelas

Autertencia legitica: Este producto contiene acataminotén. Puede occurir daño hepático grave si au hijo la toma. Ille nião de 5 dais en 24 horas, que as la cardidad daria máxima permitida. Ill con otros fármazco que confiene acataminotén Martia sobre alergia: El acataminotín puede causar resociones cutámeas garaes. Entre los antomas es podrán presentar. Ill enrejacimiento de la piel Ill ampolae Ille acentena. Si se produce una rescución cutámea, de jele de tomar el fármazo y souda a un médico de immediato.

scuoa a un marico de inmersano. Advertencia sobre el dolor de gargantar. Si el dolor de garganta es grave, persiete por más de 2 días, está acompañado de febre o es posterior a esta, dolor de cabeza, esantema, násueas o vémitos, consulte a un médico de inmediato.

No temaer — El con cualquier orto timmaco que contenga acetaminofén (con o sin receta), Si no está segur o de que un timmaco contenga acetaminofén no no, consulte con un médico d'ammacietico. — is su un ligida alguna vez ha presentado uma reacción aléngica a este producto o a cualquiera de sus ingredientes Consulte con un médico antes de tomarlo si su hijo/a tiene enfermedad hecática 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

Deje de tomanto y consulte con un médico si ■el dolor empeora o dura más de 5 días ■la fiebre empeora o dura más de 3 días ■ ocumen nuevos sintomas ▶

Información sobre el fármaco (continuación) III presenta enrojecimiento o hinchazón. Estos signos podrian indicar una afección grave.

ponanimo car una accom gare. Muntener fuen de latorare de los niños. Advertencia de sobredosis: En caso de sobredosis, tuaque asistencia médica o contáctese in mediatamente con el Centro de Contro l'Oxicológico (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 adutos — en o administrar náse de lo indicado (ver advertencia de sobredosis) — Bagile bien antes de usar — en la militro — en contre la desia afecunda en la baba. Se epocible, use el posa para calcular la dostis, de lo contrario, use la edad. El etimo el aire de la jarriaga. Inserte la punta de la jarriaga en la bosa del frasco. — El pre el hasco bacia abajo. Tire de la parte a manifa del ajeringa hasca la frase de la crimera notas rulpos del presenda por la presenda por la manifa del ajeringa hasca la frase de la crimera notas rulpos colones de moduros. linea 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 permanecca en la desis correcta ■ dispense el líquido lentamente en la boca del niño hacia la mejilla interna ■ repita la desis cada 4 horas mientras permanezcan los aintomas — no administre la dosis más de 5 vecas en 24 horas — El vuelva a colocar la tapa firmemente era que siga siendo resistente a los niños Tabla de administración de la des

lana de adilitilio da cioli de la docio			
Peso (lb)	Edad (años)	Dosis (ml)*	
menos de 24	menos de 2 años	consulte con su médico	
24-35	2-3 arios	5 ml	

o según se lo indique su médico Atención: use solamente la jeringa adjunta especificamente diseñada para ser usada con este producto. No use ningún otro dispositivo de administración de dosis.

Otra información ■almacene entre 20 y 25°C (88 y 77°F) ■ nousar si no tiene precinto in preso o si este está roto

Ingredientes inactivos ácido citrico anhidro, aufato de calcio, carragenano, rojo 40 FD&C, aaborizante, glicarina, jarabe de maiz alto en fructosa, hidroxietilcelulosa, celulosa microcristalina y carboximetilcelulosa.sódica, propilenglicol, agua punificada, benzoato de sodio, solución de sorbitol, osfato sódico tribase

¿Preguntas o comentarios?1-800-719-9290

NDC 0363-0161-94

Walgreens 🍓

Walgreens the active ten

omparación con el ingredie ctivo de Infants' Tylenol⁸¹¹

Infants' Pain & Fever Dolor & Fiebre en Bebés

ACETAMINOPHEN 160 mg PER 5 mL ORAL SUSPENSION ACETAMINOFÉN 160 mg POR CADA 5 ml SUSPENSIÓN ORAL PAIN RELIEVER / FEVER REDUCER Para aliviar el dolor / Reducir la Fiebre



Ibuprofen Free Sin ibuprofeno Paraben Free Sin parabenos

AGES 2-3 YEARS

Para 2 a 3 años de edad

2 FL 0Z (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 eleterer esia información

Drug Facts

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

Uses temporarily: Ereduces fever Erelieves minor aches and pains due to: Ethe common cold Ethu Etheadache Esore throat Etoothache

Warnings

- Liver warning: This product contains acetaminophe
- Liver warning: This product contains a setaminophen. Severe liver dange may occur if your child takes Ill more than 5 does in 24 hours, which is the maximum daily amount. Ill with other drugs containing actes an implement may cause severe skin reactions. Symptom may include: Ill skin reddering Ill tilses: Ill real Hill skin reaction occurs, stop use and seek medical helpight ways. Sore throat warning: If one throat is severe, presists for more than 2 days in accommodate of this web.
- 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 be not use a wind any owner drug containing acataminophen (peacorphion or morprescription), if you are not sure whether admy contains acataminophen, ask a doctor or pharmosist. If your child have we had an aller gic 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 thirning drug warfarin
- crime is caving the cool in intring drug was aim.

 When using this product do not exceed
 recommended dose fee overdose warming)

 Stop use and aska doctor if Ill poingets worse or
 lasts more than 5 days. Ill feer gets worse or lasts
 more than 3 days. Ill never gets worse or lasts
 more than 3 days. Ill never gets worse or lasts
 more than 3 days. Ill never gets worse or lasts
 some 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 orbical wen 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)

state well before using

m.L. = militar

find right dose on chart if possible, use weight to dose; otherwise, use age. Ill push air out of syringe. Insert syringe tip into bortle opening. Ill flip bortle upside down. Pull yellow part of syringe to the first dose line and then push product back into bottle.







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: 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)	
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: K6790BS311)	
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 Walgreen Company