

PAIN AND FEVER CHILDRENS- acetaminophen liquid

Productos Zapotol Corp.

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.

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily reduces fever
- temporarily 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. Symptom 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 non prescription). If

you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- 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

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days

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 (1-800-222-1222) right away. 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 take more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor
- find the right dose on chart below. If possible, use weight to dose: otherwise, use age.

Weight (lb)	Age (years)	Dose (mL)*
under 24	under 2	ask a doctor
24-35	2-3	5 mL
36-47	4-5	7.5 mL

48-59	6-8	10 mL
60-71	9-10	12.5 mL
72-95	11	15 mL

*or as directed by a doctor

Other information

- **each 5 mL contains:** sodium 2 mg
- store between 20-25°C (68°-77°F).
- Do not refrigerate.
- see bottom panel for lot number and expiration date

Inactive ingredients

butyl paraben, carboxymethylcellulose sodium, citric acid, D&C red #33, FD&C red #40, flavour, glycerin, high fructose corn syrup, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments?

Call **1-888-927-6865**

Principal Display Panel

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

Acetaminophen 160 mg/5mL

For ages 2-11 years

Children's

- **Pain**
- **Fever**

Bubble gum flavor

Oral suspension

ALCOHOL, ASPIRIN & IBUPROFEN FREE

fl oz (mL)

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

Distributed by

Zapotol Corp,

Package Label

Drug Facts (continued)

Find the right dose on chart below. If possible, use weight to dose; otherwise, use age.

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Questions or comments? 1-888-927-8865

Datos del medicamento

Ingrediente activo (en cada 5mL) **Propósito**
 Acetaminofén 160 mg Analgésico/reduce la fiebre

Usos ■ reduce temporalmente la fiebre ■ alivia temporalmente dolores y molestias menores debido a ■ el resfriado común ■ gripe ■ dolor de cabeza ■ dolor de garganta ■ dolor de muelas

Advertencias
Advertencia del Hígado: Este producto contiene acetaminofén. Puede producir un severo daño en el hígado si su niño toma:
 ■ más de 5 dosis en 24 horas, que es la cantidad máxima diaria
 ■ con otras medicinas que contengan acetaminofén
Alerta sobre alergias: El acetaminofén puede causar reacciones severas de la piel. Los síntomas pueden incluir: ■ enrojecimiento de la piel ■ ampollas ■ sarpullido. Si ocurre una reacción de la piel, detenga el uso y busque ayuda médica de inmediato.
Advertencia sobre dolor de garganta: Si el dolor de garganta es severo, persiste por más de 2 días, está acompañado o seguido de fiebre, dolor de cabeza, sarpullido, náuseas o vómitos, consulte un médico inmediatamente.
No usar ■ con cualquier otro medicamento que contenga acetaminofén (con receta o sin receta). Si usted no está seguro si el medicamento contiene acetaminofén, pregunte al médico o al farmacéutico ■ si su niño es alérgico al acetaminofén o a cualquiera de los ingredientes inactivos en este producto
Consulte al médico antes de usar si su niño tiene enfermedad hepática. ▶

Datos del Medicamento (Continuación)

Consulte al médico o al farmacéutico antes de usar si su niño está tomando el medicamento anticoagulante warfarina.

Cuando este usando este producto, no exceda la dosis recomendada (ver la advertencia de Sobredosis).

Detenga el uso o consulte al médico si ■ aparecen nuevos síntomas ■ se presenta enrojecimiento e hinchazón ■ el dolor empeora o persiste por más de 5 días ■ la fiebre empeora o dura más de 3 días
 Estos podrían ser signos de una condición severa.

Mantener fuera del alcance de los niños. Advertencia de Sobredosis: Tomar más de la dosis recomendada (sobredosis) puede causar daño hepático. En caso de sobredosis, busque ayuda médica o contacte al Centro de Control de Envenenamiento (1-800-222-1222) inmediatamente. La atención médica rápida es crítica incluso si usted no nota ninguna señal o síntomas.

Instrucciones ■ este producto no contiene instrucciones o advertencias completas para adultos ■ no tome más de lo indicado (consulte advertencia de Sobredosis) ■ agitar bien antes de usar ■ mL = mililitro ■ use solamente el vaso dosificador proporcionado diseñado para usarlo con este producto. No usar ningún otro dispositivo de dosificación. ■ si es necesario, repita la dosis cada 4 horas mientras los síntomas perduren ■ no suministrar más de 5 veces en 24 horas ■ no suministrar más de 5 días a menos que sea indicado por un médico ■ encuentre la dosis correcta en la siguiente tabla. Si es posible, use el peso para la dosis; de lo contrario, use la edad.

Peso (libras)	Edad (años)	Dosis (mL)*
menos de 24	menos de 2	pregunte al médico
24-35	2-3	5 mL
36-47	4-5	7.5 mL
48-59	6-8	10 mL
60-71	9-10	12.5 mL
72-95	11	15 mL

*o como lo indique el médico

Otra información ■ cada 5 mL contiene: 2 mg de sodio ■ almacenar entre 20-25°C (68-77°F) ■ no refrigerar ■ ver el panel inferior para el número de lote y la fecha de vencimiento

Ingredientes inactivos butylparaben, carboximethylcellulosa sódica, ácido cítrico, D&C rojo #33, FD&C rojo #40, sabores, glicerina, jarabe de maíz alto en fructosa, celulosa microcristalina, propilenglicol, agua purificada, benzoato de sodio, sorbitol, sucralosa, goma xantana.

¿Preguntas o comentarios? 1-888-927-8865

**Este producto no es elaborado o distribuido por McNeil Consumer Healthcare, distribuidor de Tylenol® Suspension Oral para niños.

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

zapotel
NDC 59428-281-04

New

New Melubryna

Acetaminophen 160mg/5mL
For ages 2-11 years

Para niños
 ☺ Analgésico
 ☺ Reduce la fiebre
 ☺ Children's
 ☺ Pain Reliever
 ☺ Fever Reducer

Bubble gum flavor
Oral suspension

ALCOHOL, ASPIRIN & IBUPROFEN FREE

4 fl oz (118 mL)

Drug Facts

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Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash
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 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 ■ new symptoms occur ■ redness or swelling is present ■ pain gets worse or lasts more than 5 days ■ fever gets worse or lasts more than 3 days
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Distributed by / Distribuido por
 Products Zapotel Corp.
 38850 20th St E, Palmdale, CA 93550
 888-927-8865

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Lot No.:
Exp. Date:

NEW MELUBRYNA Children's Pain Reliever Fever Reducer

PAIN AND FEVER CHILDRENS

acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59428-281
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
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59428-281-04	1 in 1 BOX	03/31/2018	03/31/2025
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 not final	part343	03/31/2018	03/31/2025

Labeler - Productos Zapotol Corp. (186063850)

