

INFANTS TYLENOL- acetaminophen suspension
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

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.

Infants' TYLENOL

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 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

- 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 for adults as well as for children 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 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) *
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under 24	under 2 years	ask a doctor
24-35 lbs	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 between 20-25°C (68-77°F)
- **do not use if carton tape or bottle wrap imprinted with "TYLENOL" is broken or missing**

Inactive ingredients

anhydrous citric acid, FD&C red no. 40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

call **1-800-458-1635** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

NDC 50580-325-01

Infants'
TYLENOL®
For Children

Acetaminophen
160 mg per 5 mL
Oral Suspension
Pain Reliever-Fever Reducer

Pain+Fever

Infants

Alcohol Free

Ibuprofen Free

Aspirin Free

No Parabens

Cherry Flavor

SimpleMeasure®
Specially designed for younger children

2 fl oz (60 mL)

160 mg per 5 mL*

Use Only Enclosed Syringe

*Same as Children's TYLENOL



How can we help?
 ¿Cómo podemos ayudarte?
 ☎ 1-800-458-1635

NDC 50580-325-01

Infants' TYLENOL®

For Children

Para niños

Acetaminophen

160 mg per 5 mL

Oral Suspension

Pain Reliever-Fever Reducer

Acetaminofén

160 mg cada 5 mL

Suspensión oral

Alivia el dolor y baja la fiebre

Pain + Fever

Dolor + Fiebre

Infants

Bebés

Alcohol Free

Sin alcohol

Ibuprofen Free

Sin ibuprofeno

Aspirin Free

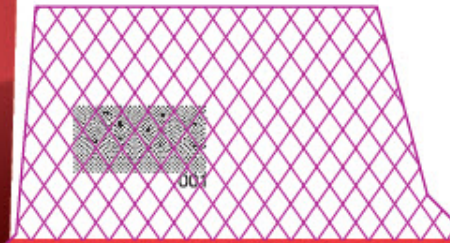
Sin aspirina

No Parabens

Sin parabenos



Cherry



Drug Facts

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Cherry Flavor
Sabor a cereza

SimpleMeasure[®]

Specially designed for younger children
Especialmente diseñado para los niños
más pequeños

2 fl oz (60 mL)
160 mg per 5 mL*

Use Only Enclosed Syringe
Utiliza solamente la jeringa provista

*Same as Children's **TYLENOL**
*Igual que Children's **TYLENOL**

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 correct dose →

LOT:

EXP:

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McNeil Consumer Healthcare Division
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USA
691287
902

Drug Facts (continued)

■ 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)*
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Other information ■ store between 20-25°C (68-77°F) ■ do not use if carton tape or bottle wrap imprinted with "TYLENOL" is broken or missing

Inactive ingredients anhydrous citric acid, FD&C red no. 40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium.

Información del medicamento (continuación)

Centro de Control Toxicológico. (1-800-222-1222) La atención médica inmediata es esencial tanto para adultos como para niños, incluso si no se observan signos ni síntomas.

Indicaciones ■ este producto no contiene indicaciones ni advertencias completas para el uso en adultos. ■ no le des más cantidad que la indicada (ver la advertencia sobre sobredosis)
■ agita bien antes de usar ■ mL = mililitro
■ encuentra la dosis correcta en la tabla siguiente. Si es posible, usa el peso para buscar la dosis; de lo contrario, usa la edad. ■ saca el aire de la jeringa. Introduce el extremo de la jeringa en la abertura del frasco
■ da vuelta el frasco boca abajo. Hala de la parte amarilla de la jeringa hasta medir la dosis correcta ■ administra el líquido despacio en la boca del niño, hacia el interior de la

purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Questions or comments? call 1-800-458-1635 (toll-free) or 215-273-8755 (collect)

Información del medicamento

Ingrediente activo (cada 5 mL)

Objetivo

Acetaminofén 160 mg Alivia el dolor y baja la fiebre

Usos temporarios: ■ baja la fiebre ■ alivia dolores menores producidos por:
■ resfriado común ■ gripe ■ dolor de cabeza ■ dolor de garganta
■ dolor de muelas

Advertencias

Advertencia sobre el hígado: Este producto contiene acetaminofén. Tu hijo puede sufrir lesiones hepáticas graves si toma ■ más de 5 dosis en 24 horas, que es la cantidad diaria máxima ■ con otros medicamentos que contengan acetaminofén

Alerta sobre alergias: el acetaminofén puede causar reacciones graves en la piel. Los síntomas pueden incluir: ■ enrojecimiento de la piel ■ ampollas ■ sarpullido. Si se produce una reacción cutánea, suspende el uso y busca ayuda médica de inmediato.

Advertencia sobre el dolor de garganta: si el dolor de garganta es intenso, dura más de 2 días, va acompañado o seguido de fiebre, dolor de cabeza, sarpullido, náuseas o vómitos, consulta con un médico de inmediato.

No lo uses ■ con cualquier otro medicamento que contenga acetaminofén (recetado o de venta libre). Si no estás seguro de si un medicamento contiene acetaminofén, consulta con un médico o farmacéutico. ■ si tu hijo es alérgico al acetaminofén o a cualquiera de los ingredientes inactivos de este producto

Consulta con un médico antes de usarlo si tu hijo tiene una enfermedad hepática

Consulta con un médico o farmacéutico antes de usarlo si tu hijo está tomando el medicamento anticoagulante warfarina

Al usar este producto, no superes la dosis recomendada (consulta la advertencia de sobredosis)

Suspende el uso y consulta con un médico si ■ el dolor empeora o dura más de 5 días ■ la fiebre empeora o dura más de 3 días ■ se presentan nuevos síntomas ■ se presenta enrojecimiento o inflamación. Estos signos podrían indicar una enfermedad grave.

Manténlo fuera del alcance de los niños. Advertencia sobre sobredosis: En caso de sobredosis, debes buscar asistencia médica o comunicarte inmediatamente con un

mejilla ■ repite la dosis cada 4 horas mientras persistan los síntomas ■ no lo uses más de 5 veces en 24 horas ■ cierra bien el frasco para que el niño no pueda abrirlo

Tabla de dosificación

Peso (lb)	Edad (años)	Dosis (mL)*
menos de 24	menos de 2 años	consulta con el médico
24-35 lbs	2-3 años	5 mL

*o la cantidad indicada por el médico

Atención: usa únicamente la jeringa provista que ha sido diseñada específicamente para usarse con este producto. No uses ningún otro dosificador.

Información adicional

■ almacenar a una temperatura de 20-25°C (68-77°F) ■ no lo uses si se ha roto o falta la cinta de la caja de cartón o el envoltorio del frasco con la palabra "TYLENOL"

Ingredientes inactivos ácido cítrico anhidro, rojo N°40 FD&C, saborizantes, glicerina, jarabe de maiz rico en fructosa, celulosa microcristalina y carboximetilcelulosa sódica, agua purificada, benzoato de sodio, solución de sorbitol, sucralosa, goma xántica

¿Tienes alguna consulta o comentario?

llama al 1-800-458-1635 (número gratuito) o al 215-273-8755 (cobro revertido)



INFANTS TYLENOL

acetaminophen suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50580-325

Route of Administration	ORAL
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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)	
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)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-325-01	1 in 1 CARTON	09/25/2017	
1		60 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/25/2017	

Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 4/2022

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division