

**PEDIACARE CHILDRENS FEVER REDUCER PAIN RELIEVER CHERRY-  
acetaminophen liquid  
Strides Pharma Inc**

*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.*

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**PediaCare Childrens Fever Reducer Cherry**

**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. 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 non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- if the child is allergic to acetaminophen or any of the inactive ingredients in this product

**Ask a doctor before use if the child has** liver disease.

**Ask a doctor or pharmacist before use if the child** is taking the blood thinning drug warfarin.

**When using this product do not exceed recommended dosage (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:** 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.**
- **shake well before using.**
- find right dose on chart below. If possible, use weight to determine dose; otherwise, use age.
- only use the enclosed syringe **Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child.**
- remove cap and insert syringe into hole at top of bottle and turn upside down.
- pull back syringe until filled to the prescribed level. If you pass the prescribed level, simply push syringe back in until you have reached the desired level. Slowly dispense the liquid into your child's mouth (towards inner cheek).
- if needed, repeat dose every 4 hours while symptoms last
- do not use more than 5 times in 24 hours (see overdose warning)
- do not give more than 5 days unless directed by a doctor
- replace cap tightly to maintain child resistance
- ml = millilitre

<b>Weight (lbs)</b>	<b>Age (yrs)</b>	<b>Dose (mL)</b>
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 ml

**Other Information**

- store at 20-25°C (68-77°F)
- **tamper evident: do not use if printed seal on bottle is broken or missing**

**Inactive Ingredients**

citric acid , FD&C red no.40, flavors, glycerine, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, potassium sorbate, purified water, sorbitol, sucralose, xanthan gum

**Questions**



**KEEP CARTON FOR FULL INFORMATION 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 • 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

**CONSERVE LA CAJA PARA VER LA INFORMACION COMPLETA**  
**Información del medicamento**  
**Ingredientes activo (por cada 5 mL):** Propósito  
 Acetaminofén 160 mg Alivia el dolor/ reduce la fiebre

**Usos** temporalmente reduce la fiebre  
 temporalmente alivia los dolores menores debidos a:  
 • resfriado común • influenza  
 • dolor de cabeza • dolor de garganta

**Advertencias**  
**Advertencia sobre el hígado:** Este producto contiene acetaminofén. Puede causar daño grave al hígado si su niño toma más de 5 dosis en 24 horas, que es la máxima cantidad diaria de otras medicinas que contienen acetaminofén.  
**Advertencia sobre las alergias:** El acetaminofén puede causar reacciones graves en la piel. Los síntomas pueden incluir:  
 • enrojecimiento de la piel • ampollas • erupciones. Si ocurre una reacción en la piel suspenda el uso y consulte de inmediato a un médico.  
**Advertencia sobre el dolor de garganta:** Si el dolor de garganta es fuerte, continúa por más de 2 días o está acompañado o seguido de fiebre, dolor de cabeza, erupciones, náusea o vómito, consulte de inmediato a un médico

**No lo use:** con ninguna otra medicina que contenga acetaminofén (con o sin receta). Si no sabe si una medicina contiene acetaminofén, pregúntele al médico o farmacéutico. Si el niño es alérgico al acetaminofén o a alguno de los ingredientes inactivos de este producto. **Consulte al médico antes de usar si el niño tiene enfermedades del hígado. Consulte al médico o farmacéutico antes de usar si el niño está tomando el anticoagulante llamado warfarina.**  
**Cuando use este producto no exceda la dosis recomendada (ver advertencia sobre las sobredosis). Suspenda el uso y consulte al médico si el dolor empeora o dura más de 5 días. La fiebre empeora o dura más de 3 días. Si surgen nuevos síntomas. Hay enrojecimiento o hinchazón. Estos podrían ser síntomas de una enfermedad grave. Mantener fuera del alcance de los niños. Advertencia sobre las sobredosis:** Tomar más de la dosis recomendada (sobredosis) puede causar daño al hígado. En caso de sobredosis busque atención médica o llame inmediatamente al Centro de Control de Envenenamiento (1-800-222-1222). Es esencial obtener atención médica rápidamente aunque no note ningún signo o síntoma.

**Instrucciones** este producto no incluye instrucciones ni advertencias completas para usarlo en adultos. **agite bien antes de usar** busque la dosis correcta en la tabla que aparece abajo. Si es posible, use el peso para determinar la dosis; si no, use la edad. **use solamente la jeringa incluida. Al administrarle este medicamento a su niño no use ninguna otra jeringa, gotero, cucharita ni otros métodos para medir la dosis.** Quite la tapa, inserte la jeringa en la abertura superior del frasco e invértalo

hale la jeringa hasta que se llene al nivel indicado. Si va más allá del nivel indicado, simplemente empuje la jeringa hasta alcanzarlo. Vierta lentamente el líquido en la boca del niño (apuntando hacia el interior de la mejilla). Si hace falta, repita la dosis cada 4 horas mientras duren los síntomas. No administre más de 5 veces en 24 horas (ver advertencia sobre las sobredosis). No administre por más de 5 días a menos que lo indique el médico. **apriete bien la tapa para que se mantenga a prueba de niños.** mL = mililitros

Peso (lbs)	Edad (años)	Dosis (mL)
menos de 24	menos de 2	pregúntele al médico
24 a 35	2 a 3 años	5 mL

**Datos adicionales** SELLADO PARA SU SEGURIDAD: NO LO USE SI EL FRASCO NO TIENE EL SELLO IMPRESO O SI EL SELLO ESTÁ ABIERTO. Guardar a temperaturas de 20° a 25°C (68° a 77°F)

**Ingredientes inactivos** ácido cítrico, FD&C rojo no. 40, sabores, glicerina, jarabe de maíz con alto contenido de fructosa, celulosa microcristalina y carboximetilcelulosa de sodio, sorbato de potasio, agua purificada, sorbitol, sucralosa, xantano

**Preguntas?** 1-888-474-3099 PediaCare.com

a drug contains acetaminophen, ask a doctor or pharmacist. If the child is allergic to acetaminophen or any of the inactive ingredients in this product, ask a doctor before use. If the child has liver disease, ask a doctor or pharmacist before use. If the child is taking the blood thinning drug warfarin. When using this product do not exceed recommended dosage (see overdose warning). Stop use and ask a doctor if pain gets worse or lasts for more than 5 days. Fever gets worse or lasts for 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:** 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. Shake well before using. Find the right dose on chart below. If possible, use weight to determine dose; otherwise, use age. Only use the enclosed syringe. Do not use any other syringe, dropper, spoon, or dosing device when giving this medicine to your child. Remove cap and insert syringe into hole at top of bottle and turn upside down. Pull back syringe until filled to the prescribed level. If you pass the prescribed level, simply push syringe back in until you have reached the desired level. Slowly dispense the liquid into your child's mouth (toward inner cheek). If needed, repeat dose every 4 hours while symptoms last. Do not give more than 5 times in any 24-hour period (see overdose warning). Do not give for more than 5 days unless directed by a doctor. Replace cap tightly to maintain child resistance. mL = milliliters

Weight (lbs)	Age (yrs)	Dose (mL)
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL

**Other information** store at 20-25°C (68-77°F). Tamper evident: do not use if printed seal on bottle is broken or missing.

**Inactive ingredients** citric acid, FD&C red no. 40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, potassium sorbate, purified water, sorbitol, sucralose, xanthan gum

**Questions?** 1-888-474-3099 Monday - Friday 8 am - 5 pm eastern standard time PediaCare.com

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PEDIACARE CHILDRENS FEVER REDUCER PAIN RELIEVER CHERRY acetaminophen liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59 556-854
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)		
	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
	FD&C RED NO. 40 (UNII: WZB9127XO A)		
	GLYCERIN (UNII: PDC6A3C0OX)		
	HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
	MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
	SORBITOL (UNII: 506T60A25R)		

<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-854-60	59 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	07/08/2010	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/08/2010	

**Labeler** - Strides Pharma Inc (078868278)

### Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	MANUFACTURE(59556-854)

Revised: 7/2017

Strides Pharma Inc