DR. SANA PAIN AND FEVER FOR CHILDREN- acetaminophen syrup GADAL Laboratories, Inc

DR. SANA® PAIN & FEVER SYRUP Children

Drug Facts

Active Ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

pain relief, 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 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

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

Do not give more than directed, this product does not contain directions or complete warnings for adult use, find right dose on chart below. If possible, use weight to dose; otherwise, use age. Repeat dose every 4 hours while symptoms last, do not give more than 5 times in 24 hours.

mL=milliliter

Weight (lb)	Age (yr)	Dose (mL) *
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL
36-47	4-5 years	7.5 mL
48-59	6-8 years	10 mL
60-71	9-10 years	12.5 mL
72-95	11 years	15 mL

Other information:

- Store between 20-25°C (68-77°F)
- Don't use if carton tape or bottle wrap imprinted with is broken or missing

Inactive Ingredients

Citric acid, corn syrup, FD&C red no. 40, glycerin, hydroxyethyl cellulose, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sorbitol solution, natural and artificial strawberry flavor, sucralose.

Questions or comments?

Call weekdays from 9:30 AM to 5 PM EST at Tel: 305-633-7900

- Fever Reducer
- Pain Reliever
- NO ALCOHOL NO GLUTEN

SHAKE WELL BEFORE USING

Distributed by:

Healthtex Distributors, LLC

Made in USA

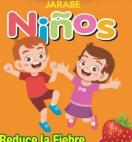
Packaging

Outer Package Label





ACETAMINOFÉN - Analgésico, Reductor de fiebre



- Reduce la Fiebre • Analgésico
- Acetaminofén 160 mg por cada 5 mL
 - SIN ALCOHOL SIN GLUTEN

Drug Facts

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But not use its Will have other drug containing aretaminophen prescription or

any of the inactive ingredients in this product.

Ask a doctor if your child has liver disease.

Ask a doctor or pharmacist before use if your child is taking the blood

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PAIN & FEVER

ACETAMINOPHEN - Pain relief, Fever reducer



- Fever Reducer
- Pain Reliever
- Acetaminophen 160 mg per 5 mL
 - NO ALCOHOL NO GLUTEN

6 FL, OZ. (180 ML)

Datos Farmacológicos

Ingrediente Activo (en cada 5 mL)

Usos temporalmente: ■ reduce la fiebre ■ alivia los dolores y mo gripe ■ tos ■ dol or de cabeza ■ dolor de gar

Advertencias
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Advertencia de higade: Este producto contiene acetaminorién. Puede
producir daño hepático grave si su hijlo toma ∎más de 5 dosis en 24 hor
que es la cantidad máxima diaria ≡ con otros medicamentos que conten

acetaminolén.

Alerta de alergia: El acetaminolén puede causar reacciones cutáneas graves Los sintomas puede incluir: menrojecimiento de la piel manpolias maspullos Si se produce una reacción en la piel, pare su uso y busque ayuda médica de inmendiato.

Immediats. Advertencia de dolor de garganta: Si d dolor es intenso, persiste más de 2 días, está acompañado o seguido de fiebre, dolor de cabeza, seguildo, natura de la compañado o seguido de fiebre, dolor de cabeza, seguildo, natura de la compañado de seguido de immediato. No utilibre en Com cualquier dos medicamento que contenga acetaminofie, con a sin recetal, à los está seguino de al un medicamento contiene acetaminofie, consulte a un médico o formacelation. Si Si su hije es defigire, apracelation de su disputador de formacelation se acetaminofie, consulte a un médico o formacelation.

Pregúnte a un médico si su hijo tiene una enfermedad hepática.

Pregúnte a un médico o farmacéutico antes de usar si su hijo esta tomando warfarina, un anticoagulante.

contanto warrante, ur amorcagnante.

Cuando use este producto, no exceda la desis recomendada.

Suspenda su uso y pregintele al médica es si didor empero a oura mas de

Sidisa es la felore emperor a oura más de 3 dias esparecen nuevos sintomas

si hay enrujecimiento o hinchazón. Estos podrian ser signos de uma afección grave

Mantener tuera del alcance de los niños. Alarta de sobredosis En caso de sobredosis, obtenga ayuda médica o comuniquese con un Centro de contrel de intoxicaciones de imedida (1, 600-222-1222) la atención médica rápida es fundamental tanto para adultos como para niños, incluso si no nota ningún

Indicaciones: No use más de le indicado, este producto no contiene instrucciones o advertencias completas para uso en adultos. Mire la dosis correcta en el cuadro a continuación. Si es posible, use peso para dosificar de lo contraro, utilize la edad. Repetra la dosis cada 4 horas mientras durer los síntomas, no dar más de 5 veces en 24 horas.

		■ mL=mililitros
Peso (lb)	Edad (años)	Dosis (mL) *
debajo de 24	menor a 2 años	pregunte a un médico
24-35	2-3 años	5 mL
36-47	4-5 años	7,5 mL
48-59	6-8 años	10 mL
60-71	9-10 años	12.5 mL
70.05	44 0300	1E onl

Otra Información: ■ almacenar entre 20-25°C (68-77°F)
■ no lo use si la cinta de cartón o el envoltorio de la botella están rotos o faltan.

¿Preguntas o comentarios? Llame de lunes a viernes de 9:30 am a 5 pm ESTE al Teléfono: 305-633-7900

info@healthtexusa.com Miami, Florida 33742 Distributed by:

Healthtex Distributors, LLC





Inner Package Label



DR. SANA PAIN AND FEVER FOR CHILDREN

acetaminophen syrup

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53113-516

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 CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) CORN SYRUP (UNII: 9G5L16BK6N) FD&C RED NO. 40 (UNII: WZ B9127XOA) GLYCERIN (UNII: PDC6A3C0OX)

HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)

METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

PROPYLPARABEN (UNII: Z8IX2SC10H)

WATER (UNII: 059QF0KO0R)

SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)

SORBITOL SOLUTION (UNII: 8KW3E207O2)

SUCRALOSE (UNII: 96K6UQ3ZD4)

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-516- 06	1 in 1 BOX	04/14/2025	
1		180 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	04/14/2025	

Labeler - GADAL Laboratories, Inc (841305639)

Establishment				
Name	Address	ID/FEI	Business Operations	
GADAL Laboratories, Inc		841305639	manufacture(53113-516)	

Revised: 7/2025 GADAL Laboratories, Inc