

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

Miami, Florida 33142
info@healthtexusa.com

Made in USA

Packaging

Outer Package Label



Drug Facts

Active Ingredient (in each 5 mL) **Purpose**
Acetaminophen 160 mg **pain relief, fever reducer**

Uses temporarily:

- reduces fever
- relieves minor aches and pains due to:
 - the common cold
 - 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)

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LOT#
EXP#

SHAKE WELL BEFORE USING

PAIN & FEVER

SYRUP

Children

- Fever Reducer • Pain Reliever
- Acetaminophen

160 mg per 5 mL

• NO ALCOHOL • NO GLUTEN

6 FL. OZ. (180 mL)

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

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Made in
USA

Distributed by:
Healthtex Distributors, LLC
 Miami, Florida 33142
 info@healthtexusa.com

acetaminophen syrup

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-516
Route of Administration	ORAL		

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CORN SYRUP (UNII: 9G5L16BK6N)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
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			

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