

SANAR NATURAL- acetaminophen solution

Evi Labs

Flavor, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium carboxymethylcellulose and sucralose

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes

- more 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.

Purpose

Pain reliever/Fever reducer

Active Ingredient

Acetaminophen 160 mg

Do not use

Do not use

with any other drug containing acetaminophen (prescription or no 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

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 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 below. If possible, use weight to dose; otherwise, use age.

Remove the child protective cap and squeeze your child's dose into the dosing cup. Repeat dose every 4 hours while symptoms last, do not give more than 5 times in 24 hours.

Weight(lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL
36-47 lbs	4-5 years	7.5 mL
48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL
75-95 lbs	11 years	15 mL

*or as directed by a doctor

Attention use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Dosage & Administration

Shake well before using. mL=milliliter. Find right dose on chart below. If possible, use weight to dose; otherwise, use age.

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Indications & Usage

reduces fever
relieves minor aches and pains due to:
the common cold
flu
headache
sore throat
toothache



Service Rep : Danielle Dombroski
 (407) 339-2626 ext. 8161
 Pre-Press : Tim Biggins EP #: 293480

Changes or revisions, other than to correct errors or omissions by Consolidated Label, may result in additional charges.
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Item #: 416936-NJ	Proof #: 4	2/2/2024 9:28:57 AM	
Sanvall Enterprises, Inc.		Sanar Naturals Childrens Acetaminophen 4fl oz - Grape Rev 2/24	
Customer Part #: LS324			
Size: 2.2500 X 5.5000			
Material: *Semi-Gloss FSC® Paper			
Top Coating: Gloss Self Wound Lamination 404/B9077/ 100			
Color Palette			

5.5 in

DIELINE DOES NOT PRINT

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 3 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)

CHILDREN'S
Acetaminophen (160 mg per 5 mL)
Pain Reliever-Fever Reducer

PAIN + FEVER
Ages 2-11 Years

4 fl oz (120 mL)
160 mg per 5 mL
Grape Flavor

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 below. If possible, use weight to dose; otherwise, use age. • remove the child protective cap and squeeze your child's dose into the dosing cup • repeat dose every 4 hours while symptoms last • do not give more than 5 times in 24 hours

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

*as directed by a doctor
Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device. **Other Information** each 5 mL contains: **sodium 2 mg** • store between 20-25°C (68-77°F) • **do not use if bottle wrap is broken or missing.** **Inactive ingredients** flavor, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium carboxymethylcellulose and sucralose.
 Distributed by Sanvall Enterprises Inc.
 Doral, FL 33178 USA
 sanarnaturals.com

2.25 in

acetaminophen solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84178-324
Route of Administration	BUCCAL		

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
GLYCERIN (UNII: PDC6A3C0OX)	175 mg in 5 mL
PROPYLPARABEN (UNII: Z8IX2SC1OH)	15 mg in 5 mL
METHYLPARABEN (UNII: A2I8C7HI9T)	20 mg in 5 mL
WATER (UNII: 059QF0KO0R)	4055.2 mg in 5 mL
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	37.5 mg in 5 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84178-324-01	1 in 1 CARTON	03/30/2024	
1		120 mL in 1 BOTTLE, UNIT-DOSE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	03/30/2024	

Labeler - Evi Labs (123617598)

Registrant - Luis Echeverria (123617598)

Establishment

Name	Address	ID/FEI	Business Operations
Evi Labs		123617598	manufacture(84178-324)

Revised: 3/2024

Evi Labs