SANATOS X CHILDREN- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hci liquid
Pharmadel LLC

SanaTos X Children (Apta)

Drug Facts

Active ingredients & Purposes

Active ingredient (in each 10 mL)	*Purposes*
Acetaminophen 325 mg	**Pain reliever/ fever reducer**
Dextromethorphan HBr 10 mg.....	Cough suppressant
Guaifenesin 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Nasal decongestant

Uses

- temporarily relieves these common cold/ flu symptoms:
- nasal congestion
- headache
- sore throat
- minor aches and pains
- cough due to minor throat and bronchial irritation
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

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, nausea, and vomiting, consult 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.
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child’s prescription drug contains an MAOI, ask a doctor or pharmacist before taking product.

Ask a doctor or pharmacist before use if your child is

aking the blood thinning drug warfarin.

Ask a doctor before use if your child has

- liver disease
- a cough that is accompanied with excessive phlegm (mucus)
- a persistent or chronic cough such as occurs with asthma
- heart disease
- high blood pressure
- thyroid disease
- diabetes

When using this product do not exceed recommended dosage.

- do not use more than directed

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- nervousness, dizziness, or sleeplessness occur

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 right away. Prompt 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**
- **do not give more than directed (see Overdose warning)**
- shake well before use
- children 6 to under 12 years of age: take 10 mL in dosing cup provided every 4 hours, while symptoms persist, up to 5 times a day or as directed by a doctor
- children under 6 years of age: do not use

Other information

- each 10 mL contains: **sodium 5 mg**
- store between 59-86°F (15-30°C)
- do not refrigerate

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions

+1-866-359-3478 (M-F) 9 AM to 5 PM EST or www.pharmadel.com

PACKAGE PRINCIPAL DISPLAY PANEL

SANATOS X CHILDREN

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hci liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-443
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Product Characteristics

Color	purple	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-443-04	1 in 1 CARTON	08/01/2024	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/01/2024	

Labeler - Pharmadel LLC (030129680)

Revised: 8/2024 Pharmadel LLC