

SANATOS DAY- acetaminophen, dextromethorphan hydrobromide, phenylephrine liquid
Pharmalab Enterprises 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.

Drug Facts

Active Ingredients	Purpose
(in each 15 mL tablespoon)	
Acetaminophen 325m.....	Pain Reliever/Fever Reducer
Dextromethorphan HBr 10mg.....	Cough Suppressant
Phenylephrine HCl 5mg.....	Nasal Decongestant

Uses: Temporarily relieves common cold/flu symptoms:

- Nasal Congestion
- Cough due to Minor Throat and Bronchial Irritation
- Sore Throat
- Headache
- Minor Aches and Pains
- Fever

Warnings: Do not exceed recommended dosage.

Do not give to children under 12 years of age.

Liver Toxicity may occur if:

- Recommended dosage is exceeded
- Used with other products containing acetaminophen
- Used with moderate amounts of alcohol

Alcohol Warning: If you consume 3 or more alcoholic drinks, ask your doctor whether you should take acetaminophen or other pain relievers. Acetaminophen may cause liver damage.

Sore Throat Warning: If sore throat is severe, persists for more than two days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

Do not use if you are:

- now taking a prescription monoamine oxidase inhibitor(MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for two weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have:

- Heart Disease
- Thyroid Disease
- Diabetes
- High Blood Pressure
- Trouble urinating due to enlarged prostate gland
- Cough that occurs with too much phlegm(mucus)
- Persistent or chronic cough as occurs with smoking, asthma or emphysema

When using this product, do not use more than directed

Stop Use and ask a doctor if:

- you get nervous, dizzy, or sleepless
- symptoms get worse or lasts more than 5 days(children) or 7 days (adults)
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with rash or headache that lasts. This could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions:

- take only as recommended.

See Overdose warning.

- use dose cup or tablespoon(TBSP)
- **do not use more than 5 doses(children) or 6 doses(adults) in 24 hours**

Adults and children 12 years and older: Take 2 TBSP(30ml) every 4 hours, while symptoms persist or as directed by a doctor

Children 6 to under 12 years of age: take 1 TBSP 15ml every 4 hours, while symptoms persist or as directed by a doctor

Children under 6 years of age: Consult a doctor. Do not use this adult extra strength product in children under 6 years of age. This will provide more than the recommended dose(overdose) of acetaminophen and cause serious problems.

Other information: each tablespoon contains sodium 50 mg

MISSING OR BROKEN

SanaTos™

Alcohol-Free/Antihistamine Free/Sugar Free

DAY

*Compare to Active Ingredients of Dayquil

Cold & Flu
Multi-Symptom Relief

Cherry Flavor

Pain Reliever / Fever Reducer
Analgesico / Reductor de Fiebre
Nasal Decongestant
Descongestionante Nasal
Cough Suppressant / Supresor de Tos

6 FL OZ
(177 ml)

Distributed by:
D IMPORT LLC,
Bord DE 19873
sanaTos.com
866-359-3478

Do not use if safety seal around bottle is broken or missing

Drug Facts

Active Ingredients (in each 15 mL tablespoon) **Purpose**

Acetaminophen 325 mg... Pain reliever/Fever reducer
Dextromethorphan HBr 10 mg... Cough Suppressant
Phenylephrine HCl 5 mg... Nasal Decongestant

Uses Temporarily relieves common cold/flu symptoms:
■ nasal congestion ■ cough due to minor throat
and bronchial irritation ■ sore throat ■ headache
■ minor aches and pains ■ fever

Warnings

Do not exceed recommended dosage.
Do not give to children under 6 years of age.
Liver toxicity may occur if ■ recommended dosage is
exceeded ■ used with other products containing
acetaminophen ■ used with moderate amounts of
alcohol

alcoholic drinks, ask your doctor whether
reducers. Acetaminophen may cause
ore than two days, is accompanied or
it a doctor promptly.
ine oxidase inhibitor
net conditions, or Parkinson's disease),
t know if your prescription drug
g this product.
d pressure ■ trouble urinating due
uch phlegm (mucus) ■ persistent or
ema
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gets worse or lasts more than 3 days
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Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional
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dose can cause serious health problems. In case of
overdose, get medical help or contact a Poison Control
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or as directed by a doctor

Drug Facts (continued)

Children 6 to under 12 years of age	Take 1 TBSP (15 mL) every 4 hours, while symptoms persist or as directed by a doctor
Children under 6 years of age	Consult a doctor. Do not use this adult extra strength product in children under 6 years of age. This will provide more than the recommended dose (overdose) of acetaminophen and cause serious problems.

Other information ■ each tablespoon contains
sodium 50 mg ■ store at room temperature

Inactive ingredients carboxymethylcellulose
sodium, citric acid, disodium EDTA, FD&C Yellow No. 6,
flavor, glycerin, propylene glycol, purified water,
saccharin sodium, sodium benzoate, sodium chloride,
sodium citrate, sorbitol, sucralose.

Questions? (302) 725-0692

TAMPER EVIDENT: DO NOT USE IF PRINTED SHRINKBAND IS MISSING

*"Sanatos DAY is not manufactured
distributed by Procter & Gamble distributors
of Vicks® Dayquil®"*



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Se
www.mallinc.com

PEEL BACK
FOR DRUG FACTS

SanatosTM
DAY
Acetaminophen/Antihistamine/Free/Sugar Free

**Cold & Flu
Multi-Symptom Relief**

**Pain Reliever/Fever Reducer
Cough Suppressant
Nasal Decongestant**

Drug Facts (continued)

Warnings Alcohol warning: If you consume 3 or more 2 you should take acetaminophen or other pain relievers/fever liver damage.

Sore throat warning: If sore throat is severe, persists for m followed by fever, headache, rash, nausea or vomiting, consu

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SANATOS DAY

acetaminophen, dextromethorphan hydrobromide, phenylephrine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14505-398
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
PHENYLEPHRINE (UNII: 1WS297W6MV) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor	CHERRY (CHERRY)	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14505-398-06	177 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/04/2010	

Labeler - Pharmalab Enterprises Inc (174401088)**Registrant** - Pharmalab Enterprises Inc (174401088)**Establishment**

Name	Address	ID/FEI	Business Operations
Pharmalab Enterprises Inc		174401088	manufacture

Revised: 9/2010

Pharmalab Enterprises Inc