SANATOS SEVERE COLD AND COUGH DAY TIME- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride granule, for solution
Pharmadel LLC

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.

SanaTos Severe Cold and Cough Daytime

Drug Facts

Active ingredients (in each packet)	*Purposes*
Acetaminophen 650 mg	**Pain reliever/ fever reducer**
Dextromethorphan HBr 20 mg	Cough suppressant
Phenylephrine HCI 10 mg	Nasal decongestant

Uses

Temporarily relieves common cold/flu symptoms:
- cough due to minor throat & bronchial irritation
- headache
- sore throat
- minor aches & pains
- nasal congestion due to hay fever
- other upper respiratory allergies
- sinus congestion and pressure
- stuffy nose
- reduces fever

Warnings

Liver warning: This product contains **acetaminophen**. Severe liver damage may occur if you take:
- more than 6 packets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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 you are now taking a prescription monoamine oxidase inhibitor (MAOIs) (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 prescription drug contains an MAOI, ask a

doctor or pharmacist before taking this product.
- for more than 7 days for pain and 3 days for fever, unless directed by a doctor

Ask a doctor before use if you have
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- a cough that is accompanied by excessive phlegm (mucus)
- a persistent or chronic cough as occurs with smoking, asthma or emphysema
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if
- taking the blood thinning drug warafin

Stop use and ask a doctor if
- a persistent cough or symptoms do not improve within 5 days, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- new symptoms occur
- redness or swelling is present
- nervousness, dizziness, or sleeplessness occur

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

KEEP OUT OF REACH OF CHILDREN. In case of accidental 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
- **do not exceed recommended dosage**
- take every 4 hours; do not exceed 6 packets in a 24-hour period
- dissolve contents of one packet into 8 oz. of hot water and sip while hot; consume entire drink within 10-15 minutes
- if using a microwave; add contents of one packet to 8 oz. of cool water, stir briskly before and after heating. Do not overheat.

Age	**Dose**
adults & children 12 yrs. of age & over	one packet every 4 hours
children under 12 yrs. of age	**do not use**

Other information
- **each packet contains:** potassium 10 mg, sodium 27 mg
- **phenylketonurics:** contains phenylalanine 14 mg per packet
- store at room temperature 68-77°F (20-25°C)
- protect from excessive heat and moisture

TAMPER EVIDENT: Do not use if packets are broken or torn.

Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, FD&C blue 1, FD&C red 40, flavors, isopropyl alcohol, maltodextrin, silicon dioxide, sodium citrate, sucrose, tribasic calcium phosphate, water

Questions or Comments?

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

Distributed by/ Distribuido por:
PHARMADEL

Georgetown, DE 19947

Made in India

PRINCIPAL DISPLAY PANEL

SanaTos ® Severe COLD & COUGH

NDC 55758-010-01

NDC 55758-010-06

SANATOS SEVERE COLD AND COUGH DAY TIME

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride granule, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-010
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55758-010-06	6 in 1 CARTON; Type 0: Not a Combination Product	02/20/2014	
2	NDC:55758-010-01	1 in 1 POUCH; Type 0: Not a Combination Product	02/20/2014	
3	NDC:55758-010-18	18 in 1 CARTON; Type 0: Not a Combination Product	03/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/20/2014	

Labeler - Pharmadel LLC (030129680)