SANATOS SEVERE COLD AND COUGH NIGHTTIME- acetaminophen, diphenhydramine hydrochloride, 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 Nighttime

Drug Facts

Active Ingredients (in each packet)	*Purposes*
Acetaminophen 650 mg	**Pain reliever/ fever reducer**
Diphenhydramine HCI 25 mg	Antihistamine/ cough suppressant
Phenylephrine HCI 10 mg	Nasal decongestant

Uses

Temporarily relieves common cold/flu symptoms:

- headache
- sore throat
- minor aches & pains
- nasal congestion & itchy, watery eyes due to hay fever
- other respiratory allergies
- cough due to minor throat & bronchial irritation
- itchy nose and throat
- runny nose
- sneezing
- stuffy nose
- and reduces fever

Warnings

Liver warning: This product contains **acetaminophen**. Severe liver damage may occur if you take

- more than 6 doses 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 (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 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
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a breathing problem such as emphysema
- chronic bronchitis
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- may cause excitability especially in children
- may cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages while taking this product
- use caution when driving a motor vehicle or operating machinery

Stop use and ask doctor if

- new symptoms occur
- pain or fever persists or gets worse
- symptoms do not improve within 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- if nervousness, dizziness, or sleeplessness occur

If pregnant or breast-feeding, ask a health 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 take more than 6 packets in 24- hour period
- dissolve contents of one packet into 8 oz. 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 years of age & over	one packet every 4 hours
children under 12 years of age	**do not use**

Other information

- **each packet contains:** potassium 10 mg, sodium 27 mg
- **phenylketonurics:** contains phenylalanine 13 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, D&C yellow 10, 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:

PHARMADEL

Georgetown, DE 19947

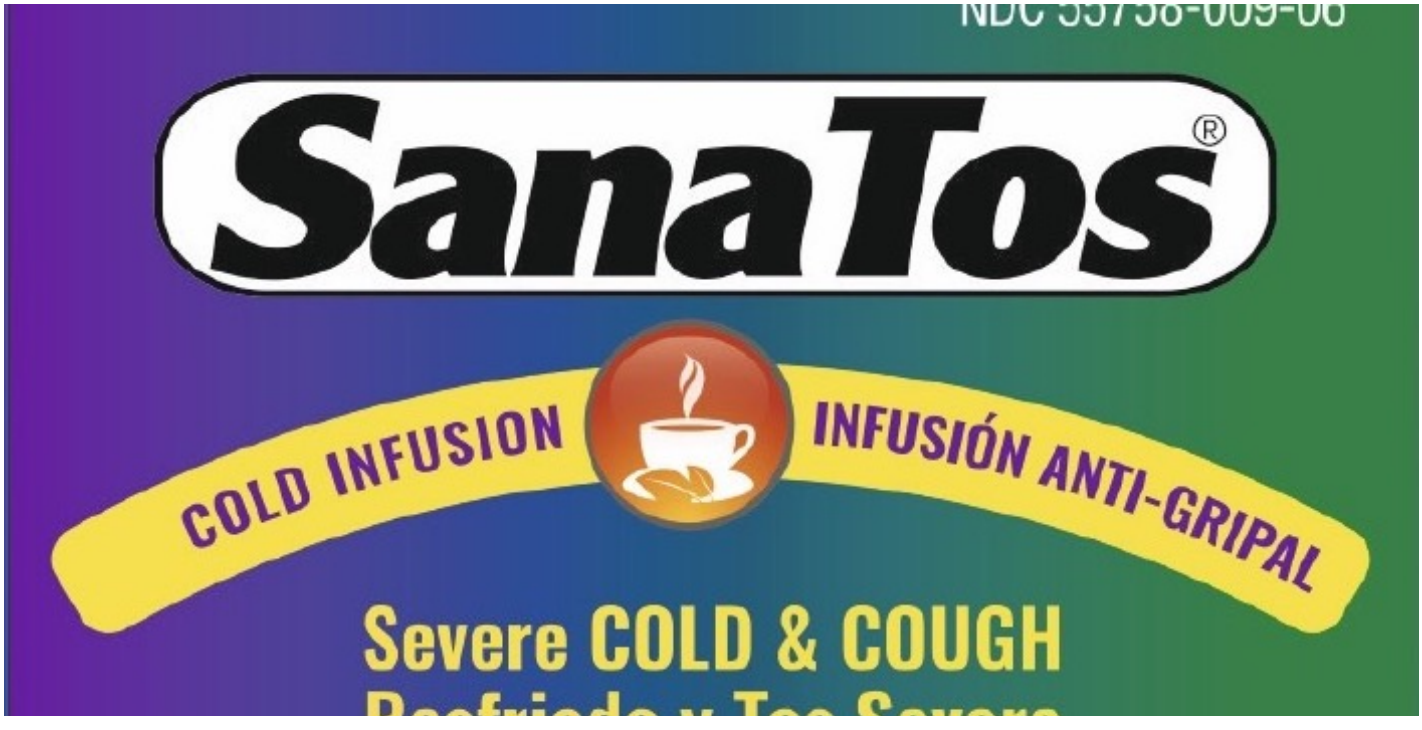
Made in India

PRINCIPAL DISPLAY PANEL

SanaTos ®Severe COLD & COUGH Nighttime

NDC 55758-009-01

NDC 55758-009-06



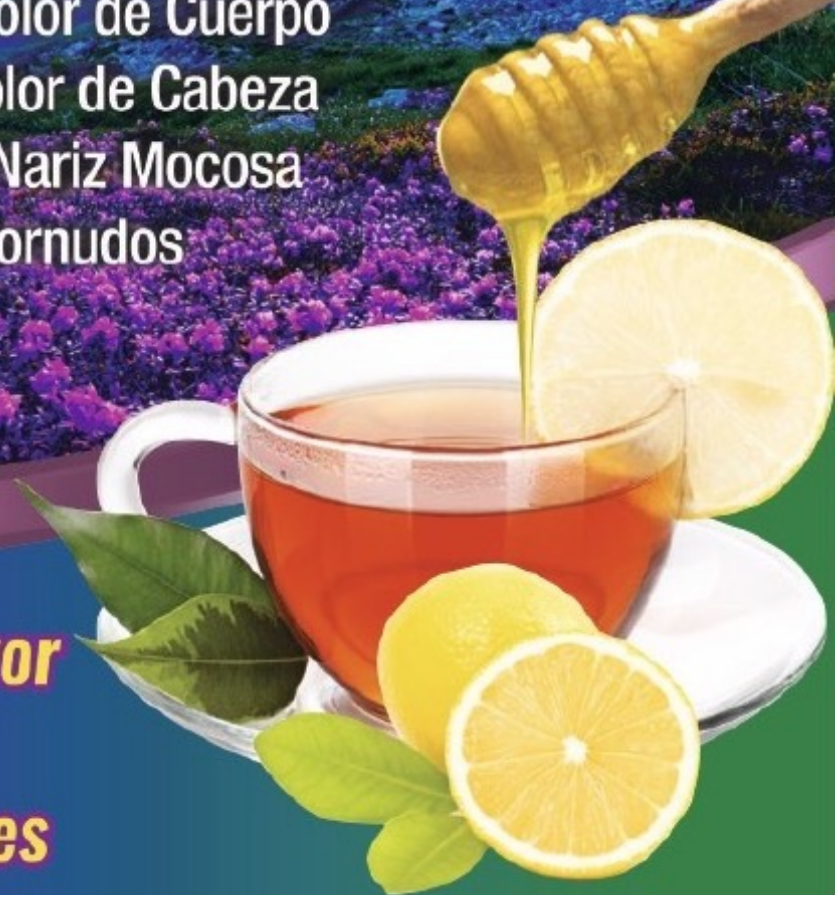
Resfriado y Tos Severa

• Acetaminophen • Diphenhydramine HCl • Phenylephrine HCl
• Acetaminafen • Difenhidramina HCl • Fenilefrina HCl

Nighttime / Noche

RELIEF / ALIVIA

- Nasal Congestion / Congestión Nasal
- Sore Throat / Dolor de Garganta
- Body Ache / Dolor de Cuerpo
- Headache / Dolor de Cabeza
- Runny Nose / Nariz Mocosa
- Sneezing / Estornudos
- Cough / Tos
- Fever / Fiebre



Lemon Honey Flavor
Sabor Limón Miel
6 Packets / Sobres

SANATOS SEVERE COLD AND COUGH NIGHTTIME

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride granule, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-009
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
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)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	HONEY, LEMON	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55758-009-06	6 in 1 CARTON; Type 0: Not a Combination Product	02/20/2014	
2	NDC:55758-009-01	1 in 1 POUCH; Type 0: Not a Combination Product	02/20/2014	
3	NDC:55758-009-18	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)

Revised: 6/2020 Pharmadel LLC