

**SANATOS SEVERE COLD RELIEF NIGHTTIME- acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride granule, for solution**  
Pharmadel LLC

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**SanaTos Nighttime EHL Powder (AS)**

***Drug Facts***

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***Active ingredients & Purposes***

<b><i>Active Ingredients (in each packet)</i></b>	<b><i>Purposes</i></b>
<b>Acetaminophen 650 mg</b>	<b>Pain reliever/ fever reducer</b>
Diphenhydramine HCL 25 mg	Antihistamine/ cough suppressant
Phenylephrine HCL 10 mg	Nasal decongestant

***Uses***

Temporarily relieves common cold/flu symptoms:

- minor aches and pains
- sore throat
- headache
- nasal congestion
- runny nose
- itchy nose and throat
- cough due to minor throat & bronchial irritation
- and temporarily 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

**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.
- with any other product containing diphenhydramine, even one used on skin

### **Ask a doctor before use if you**

- have liver disease
- have heart disease
- have high blood pressure
- have thyroid disease
- have diabetes
- have glaucoma
- have a breathing problem such as emphysema
- have difficulty urinating due to an enlarged prostate gland
- have a breathing problem such as emphysema or chronic bronchitis
- are taking sedatives or tranquilizers

### **Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin

### **When using this product**

- **do not exceed recommended dosage**
- may cause excitability, especially in children
- use caution when driving a motor vehicle or operating machinery
- may cause marked drowsiness

### **Stop use and ask doctor if**

- nervousness, dizziness, or sleeplessness occur
- redness or swelling is present
- pain, cough, or nasal congestion persists or gets worse or last more than 7 days
- fever gets worse or lasts more than 3 days
- any new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

### **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***

- dissolve one packet in an 8oz. glass of hot water. If using a microwave; add content into a glass of cool water and stir briskly before and after heating. Do not overheat.
- sip while hot and consume the entire drink within 10-15 minutes
- **adults & children 12 years of age and over:** one (1) packet every 4 hours, do not exceed **6 packets** per 24 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)
- do not use if packets are punctured or torn.

### ***Inactive ingredients***

acesulfame potassium, anhydrous citric acid, aspartame, D&C yellow #10, eucalyptus honey lemon flavors, FD&C blue #1, FD&C red #40, isopropyl alcohol, maltodextrin, silicon dioxide, sodium citrate, sucrose, tribasic calcium phosphate, water

### ***Questions?***

**+1-866-359-3478** (M-F) 9 AM to 5 PM EST or [www.pharmadel.com](http://www.pharmadel.com)

### **Distributed by:**

**PHARMADEL LC**

New Castle, DE 19720

Made in India

### **PRINCIPAL DISPLAY PANEL**

Instrucciones en Español adentro de la caja

NDC 55758-385-06



Nighttime/ Noche

Severe Cold Relief / Alivio del Resfriado Severo

Acetaminophen  
Diphenhydramine HCL  
Phenylephrine HCL

Acetaminofén  
Difenhidramina HCL  
Fenilefrina HCL

**RELIEF**

- ✔ Fever reducer
- ✔ Minor aches and pain
- ✔ Sore throat
- ✔ Headache
- ✔ Nasal congestion
- ✔ Cough
- ✔ Itchy nose or throat

**ALIVIA**

- ✔ Reduce la fiebre
- ✔ Dolores y molestias leves
- ✔ Dolor de garganta
- ✔ Dolor de cabeza
- ✔ Congestión nasal
- ✔ Tos
- ✔ Picazón en la nariz o garganta



**6** PACKETS  
SOBRES

EUCALYPTUS HONEY LEMON FLAVORS  
SABORES EUCALIPTO MIEL LIMÓN

## SANATOS SEVERE COLD RELIEF NIGHTTIME

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55758-385
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY, LEMON (Eucalyptus Honey Lemon)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-385-06	6 in 1 CARTON; Type 0: Not a Combination Product	03/31/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/31/2024	

**Labeler** - Pharmadel LLC (030129680)

Revised: 3/2024

Pharmadel LLC