

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

SanaTos Nighttime EHL Powder (AS)

Drug Facts

Drug Facts

Active ingredients & Purposes

<i>Active Ingredients (in each packet)</i>	<i>Purposes</i>
Acetaminophen 650 mg	Pain reliever/ fever reducer
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

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.
- 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.

Kepp 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 8 fl oz 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 and children 12 years of age and older:** 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

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-385
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
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

WATER (UNII: 059QF0KO0R)	
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)	

Product Characteristics

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

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)