

**SANATOS NIGHTTIME RELIEF- acetaminophen, dextromethorphan hbr,
doxylamine succinate capsule, liquid filled
Pharmadel LLC**

Sanatos Nighttime Relief (APTA)

Drug Facts

Active ingredients and Purposes

Purposes

Active ingredients(in each softgel) Purpose

Acetaminophen 325mgPain reliever/ fever reducer
Dextromethorphan HBr 20mg.....Cough suppressant
Doxylamine succinate 12.5mg..... Antihistamine

Uses

Temporarily relieves the common cold/flu symptoms associated with

- minor aches and pains
- headache
- sore throat
- runny nose
- cough due to minor throat and bronchial irritation
- sneezing
- temporarily reduces fever

Warnings

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

- more than 8 softgels 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.

Ask a doctor before use if you have

- liver disease
- glaucoma
- a persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a cough that is accompanied by excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the 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

- excitability may occur, especially in children
- marked drowsiness may occur
- alcoholic, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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 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

- if you are taking other cold/flu products, read complete labeling before dosing

Age	Dose
adults and children 12 years and older	two (2) softgels every 6 hours, do not exceed 8 softgels in 24 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

Other information

- store between 68-77°F (20-25°C)
- avoid excess heat

Inactive ingredients

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions?

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

Dist. by/ por:**Pharmadel LLC**

New Castle, DE 19947

+1-866-359-3478

†This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® Nyquil® Liquicap

Principal Display Panel

NDC 55758-515-08

†Compared to the active ingredients in Vicks® Nyquil® Cough & Flu Liquicaps®

†Comparable a los ingredientes activos de Vicks® Nyquil® Cough & Flu Liquicaps®

SanaTos®

Nighttime Relief Alivio Durante La Noche

Acetaminophen,

- Dextromethorphan HBr • Doxylamine Succinate

Acetaminofén

- Dextrometorfano HBr • Succinato de doxilamina



Cold/ Flu Relief • Alivio del Resfriado/ Gripe

- ✓ Fever/ Fiebre
- ✓ Headache / Dolor de cabeza
- ✓ Sore throat / Dolor de garganta
- ✓ Aches & Pains / Molestias y Dolores
- ✓ Sneezing / Estornudos
- ✓ Cough / Tos

8 / Softgels
Cápsulas Blandas

SANATOS NIGHTTIME RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-515
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg
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Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green (clear)	Score	score with uneven pieces
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	603
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-515-08	8 in 1 CARTON	04/01/2026	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/01/2026	

Labeler - Pharmadel LLC (030129680)

Revised: 4/2026

Pharmadel LLC