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

Sanatos Nightime Softgel (HHH Pharma)

Drug Facts

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Active Ingredients and Purposes

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Active ingredients (in each softgel)	***Purposes***
Acetaminophen 325 mg.....	**Pain reliever/ fever reducer**
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses

Temporarily relieves cough-cold symptoms
- cough due to minor throat and bronchial irritation
- headache
- minor aches and pains
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever
- 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 for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert: Acetaminophenmay cause severe skin reactions. Symptoms may include:
- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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

Ask a doctor or pharmacist before use if you are

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

When using this product

- may cause marked drowsiness
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness effect
- avoid alcoholic drinks when taking this product
- 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
- new symptoms occur
- cough comes back or occurs with a rash or a persistent 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

Age	Dose
adults and children 12 years and older	2 softgels every 6 hours, **do not exceed 8 softgels in a 24 hour period**
children 4 to under 12 years	consult a doctor
children under 4 years	**do not use**

Other information

- store between 68-77°F (20-25°C)
- avoid excessive heat
- do not use if blister pack is punctured or torn

Inactive ingredients

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol 400, povidone k-30, propylene glycol, sorbitol sorbitan solution, water

Questions or comments?

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

Dist by/ por:

PHARMADEL LLC

New Castle, DE 19720

www.pharmadel.com

Principal Display Panel

SANATOS NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-510
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SORBITAN (UNII: 6O92ICV9RU)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green	**Score**	score with uneven pieces
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	CF02
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-510-08	1 in 1 CARTON	09/01/2025	
1		8 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	09/01/2025	

Labeler - Pharmadel LLC (030129680)

Revised: 9/2025 Pharmadel LLC