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

Sanatos Nightime Softgel (HL)

Drug Facts

Active Ingredients and Purposes

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 common cold/flu symptoms
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever
- and fever reducer

Warnings

Liver warning: This product contains **acetaminophen**. Severe liver damage may occur if you take
- more than 4 doses 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: 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.

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 3 days for fever unless directed by a doctor

Ask a doctor before use if you have
- liver disease
- glaucoma
- a cough that is accompanied by excessive phlegm (mucus)
- a breathing problem, persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to an enlarged 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
- excitability may occur, especially in children
- may cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase drowsiness effect
- avoid alcoholic drinks
- 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 5 days
- redness or swelling is present
- new symptoms occur
- cough comes back, 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 overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Other information
- store between 68-77°F (20-25°C)
- avoid excessive heat

- do not use if blister pack is punctured or torn

Directions

- **do not exceed recommended dosage (see Liver warning)**
- do not exceed 4 doses in a 24 hour period or as directed by a doctor

Age	**Dose**
adults and children 12 years and older	2 softgels every 6 hours
children 4 to under 12 years	consult a doctor
children under 4 years	**do not use**

Inactive ingredients

D&C yellow #10, FD&C blue #1, gelatin, glycerin, methylparaben, polyethylene glycol, povidone k-30, propylene glycol, propylparaben, sorbitol, titanium dioxide, water.

Questions or comments?

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

Distributed by:

PHARMADEL LLC

New Castle, DE, 19720

/PHARMADELUSA

SANATOS NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-042
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**
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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	SN3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-042-08	1 in 1 CARTON	04/04/2023	
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	04/04/2023	

Labeler - Pharmadel LLC (030129680)

Revised: 9/2024 Pharmadel LLC