# SANATOS NIGHTTIME MULTI SYMPTOMS- acetaminophen, dextromethorphan hbr, doxylamine succinate liquid Pharmadel LLC

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Sanatos MS Nighttime 6 (APTA)

## **Drug Facts**

#### **Active Ingredients & Purposes**

Active ingredients (in each 30 mL dose cup)	Purposes	
Acetaminophen 650 mg	Pain reliever/ fever reducer	
Dextromethorphan HBr 30 mg	Cough suppressant	
Doxylamine succinate 12.5 mg	Antihistamine	

#### Uses

temporarily relieves these common cold/flu symptoms:

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

## Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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.
- to make a child sleepy

## Ask a doctor before use if you have

- a sodium-restricted diet
- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to 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

- · do not use more than directed
- avoid alcoholic drinks
- excitability may occur, especially in children
- marked drowsiness may occur
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

## Stop use and ask a doctor if

- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by fever
- fever gets worse or lasts more than 3 days
- cough lasts more than 7 days, comes back, or occurs with fever, 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.

## **Overdose warning:**

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.

#### **Directions**

- take only as recommended see Overdose warning
- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hours

age	dose
adults & children 12 years & over	30 mL(2TBSP) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

• If taking Nighttime at night and Daytime during the day, limit total to 4 doses per 24 hours.

#### Other informaiton

• each 30 mL dose cup contains: sodium 45 mg

• store at room temperature

**Tamper Evident:** Do not use if imprinted shrink band is missing or broken.

## Inactive ingredients

citric acid, D&C yellow#10, FD&C Green# 3, FD&C yellow# 6, flavor, glycerin, polythylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose

#### Questions?

call 1-866-359-3478

## Distributed by:

#### **Pharmadel LLC**

Seaford, DE 19973

www.sanatos.com

## **Princpal Display Panel**



## **SANATOS NIGHTTIME MULTI SYMPTOMS**

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-056
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL		

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	green	Score	
Shape		Size	
Flavor	ANISE	Imprint Code	
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55758- 056-25	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2014			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	12/01/2014		

## Labeler - Pharmadel LLC (030129680)

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