

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

Sanatos Nighttime MS 6 (PLE)

Drug Facts

Active ingredients & Purposes

Active ingredients

(in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purposes

Pain reliever/ fever reducer

Cough suppressant

Antihistamine

Uses

Temporarily relieves 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:

- adults take more than 4 doses in 24 hours, which is the maximum daily amount
- child takes more than 3 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product

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 user

- has a sodium-restricted diet
- has liver disease
- has glaucoma
- has cough that occurs with too much phlegm (mucus)
- has a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- has trouble urinating due to enlarged prostate gland
- is a child with pain of arthritis

Ask a doctor or pharmacist before use if user is

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

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- 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 5 days (children) or 7 days (adults)
- 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

- use only dosing cup provided
- shake well before use
- if you are taking other cold/flu products, read complete labeling

adults & children 12 years & over	30 mL every 4 hours, do not exceed (child) 3 doses and (adult) 4 doses in 24 hours
children under 12 years	ask a doctor

Other information

- each 30 mL contains: **sodium 10 mg**
- store between 68-77°F (20-25°C)

Inactive ingredients

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

Questions?

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

Distributed by:

Pharmadel

New Castle, DE 19720

www.pharmadel.com

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Principal Display Panel



Nighttime Relief

NDC 55758-416-06

SanaTos[®]

MULTI-SYMPTOM COLD & FLU RELIEF

Acetaminophen • Dextromethorphan HBr • Doxylamine Succinate

- ✓ Pain & Fever
- ✓ Cough
- ✓ Sore throat
- ✓ Sneezing & Runny Nose



6 fl oz (177 mL)

SANATOS MULTI SYMPTOMS NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-416
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
WATER (UNII: 059QF0KO0R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	ANISE (Medicinal)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-416-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/01/2023	

Labeler - Pharmadel LLC (030129680)

Revised: 11/2023

Pharmadel LLC